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GERMS, VIRUSES, AND SECRETS: THE SILENT PROLIFERATION OF BIO-LABORATORIES IN THE UNITED STATES

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

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CONTENTS

Page

Hon. Bart Stupak, a Representative in Congress from the State of Michigan, opening statement 1
Hon. Joe Barton, a Representative in Congress from the State of Texas, opening statement 3
Hon. Gene Green, a Representative in Congress from the State of Texas, opening statement 5
Hon. Michael C. Burgess, a Representative in Congress from the State of Texas, opening statement 6
Hon. Marsha Blackburn, a Representative in Congress from the State of Tennessee, opening statement 8
Hon. John D. Dingell, a Representative in Congress from the State of Michigan, prepared statement 49
Hon. Ed Whitfield, a Representative in Congress from the Commonwealth of Kentucky, prepared statement 50

WITNESSES

Keith Rhodes, Chief Technologist, Center for Technology and Engineering, U.S. Government Accountability Office 10
  Prepared statement 13
Richard Besser, M.D., Director, Coordinating Office for Terrorism, Preparedness and Emergency Response, Centers for Disease Control and Prevention 67
  Prepared statement 69
Hugh Auchincloss, M.D., Deputy Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. Department of Health and Human Services 74
  Prepared statement 75
Eddie J. Davis, interim president, Texas A&M University 91
  Prepared statement 92
Gigi Kwik Gronvall, senior associate, assistant professor of medicine, Center for Biodiversity, University of Pittsburgh Medical Center 105
  Prepared statement 106
Alan Pearson, director, Biological and Chemical Weapons Control Program, Center for Arms Control and Non-Proliferation 110
  Prepared statement 112
Edward Hammond, the Sunshine Project 143
  Prepared statement 145

SUBMITTED MATERIAL

"High-Containment Biodefense Research Laboratories: Meeting Report and Center Recommendations" Gigi Kwik Gronvall, et al. 174
Subcommittee hearing exhibts 185

GERMS, VIRUSES, AND SECRETS: THE SILENT PROLIFERATION OF BIO-LABORATORIES IN THE UNITED STATES

THURSDAY, OCTOBER 4, 2007

House of Representatives,
Subcommittee on Oversight and Investigations,
Committee on Energy and Commerce,
Washington, DC.

The subcommittee met, pursuant to call, at 10:05 a.m., in room 2123 of the Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Members present: Representatives Stupak, DeGette, Green, Inslee, Burgess, Blackburn, and Barton.

Staff present: John Sopko, John Arlington, Paul Jung, Scott Schloegel, Kyle Chapman, Kristen Carpenter, Peter Spencer, and Alan Slobodin.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Stupak. Today we have a hearing on Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States. Each Member will be recognized for 5 minutes for an opening statement. I will begin.

This is the first of what will likely be several hearings this committee intends to hold to examine the risk associated with the recent proliferation of high-containment biological research laboratories. Today's hearing is focused on high-contaminate bio-laboratories known as BSL–3 and BSL–4 labs in the United States. We anticipate a future hearing will examine the proliferation of high-containment labs outside of the United States. Another hearing will examine the Department of Homeland Security's plan to close Plum Island Animal Disease Center and build a new $500 million animal research facility elsewhere, including a new BSL–4 lab.

Our hearing today will focus on the risk associated with the recent increase of domestic BSL–3 and BSL–4 labs. These BSL–3 and 4 labs are the facilities where research is conducted on highly infectious viruses and bacteria that can cause injury or death. Some of the world's most exotic and most dangerous diseases are handled at BSL–3 and 4 labs, including anthrax, foot-and-mouth disease and Ebola fever. The accidental or deliberate release of some of the biological agents handled at these labs could have catastrophic consequences. Yet, as we will hear from the Government Accountability Office, GAO, no single Government agency has the ultimate responsibility for ensuring the safety and securing of these high-containment labs. However, GAO states there is a major expansion of the number of BSL laboratories is occurring both in United States and abroad but the full extent of that expansion is unknown.

No one in the Federal Government even knows for sure how many of these labs there are in the United States, much less what research they are doing or whether they are safe and secure.

What we do know is that the Federal Government has been funding the proliferation of these labs on an unprecedented scale. For the past 5 years, the NIH has spent more than $1 billion on the construction of new BSL–3 and BSL–4 labs. Given the serious risk associated with these labs, we must ask if all these new labs are necessary. Has the NIH carefully assessed the need for these labs before writing checks to build them? Would we be better off expanding existing facilities rather than building dozens of new ones? When it comes to BSL–4 labs, which are the labs that deal with the most serious diseases for which there is no cure, should we significantly limit the number of labs so there are fewer chances for an accidental or intentional release of these most dangerous substances? Has the proliferation of these labs reached the point at which there are so many labs doing this research that you actually increase the chances of catastrophic release of a deadly disease?

Apart from the issue of mushroom growth of these labs, perhaps the most important question looming over all this is, are these labs safe? The most serious accidents so far have occurred outside the U.S., including the death of a Russian lab worker exposed to Ebola and the SARS infections that sickened several people and killed a lab worker in Asia. Here in the U.S. for the past 4 years, the CDC has received more than 100 incident reports from labs handling select agents. However, there are indications that the actual number of incidents may be much higher.

It is also alarming to note that more than a third of the incident reports are from 2007, which begs the question of why has there been such a steep increase in BSL incidents.

Federal regulations require reports only for incidents involving so called select agents, a list of highly dangerous pathogens. But other dangerous biological pathogens are not on the select agent list, such as hantavirus, SARS and dengue fever. It appears that there is no Federal oversight of the possession, use or transfer of these dreaded diseases nor is there any requirement that the theft, loss or release of these agents will be reported to Federal officials.

Even for select agents which are regulated, there may be a significant amount of under-reporting of laboratory mishaps. A case of point is Texas A&M University. Texas A&M recently reported to the CDC that one of its lab researchers had been infected in 2006 with *Brucella* and that blood tests of three other workers indicated two fever exposures. They reported the incidents only after one of our witnesses, Ed Hammond, of the Sunshine Project exposed the incidents on his Web site. The CDC's subsequent investigation of the Texas A&M lab revealed a number of serious violations of the select agent rules, including lost samples, unapproved experiments, a lack of training, safety training and lab workers without FBI clearance, which is required for working with select agents. Unfortunately, the CDC's August investigation revealed not only shortcomings at the Texas A&M University but also shortcomings on the part of CDC's own oversight. It turns out that the CDC had inspected the very same Texas A&M lab prior to the disclosure of these incidents and found only minor problems. This may indicate that the periodic lab inspections that CDC carries out may not be as thorough as one might hope.

Other recent incidents indicate additional problems presented by labs around the country. Problems at the CDC's own lab in Atlanta and recent outbreaks of foot-and-mouth disease in the UK linked to a high-containment lab at Pirbright illustrate the importance of proper laboratory design, construction and maintenance, in addition to workers' safety, worker training and security.

The potential human risk involved in high-containment laboratory biological research demand that this subcommittee take a closer look at whether these labs are being designed, constructed and operated safely. As I said, this is the first of several hearings our Oversight and Investigations Subcommittee will conduct on germs, viruses, and secrets.

With that I will yield back.

I will next turn to Mr. Barton.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Chairman Stupak, for holding this hearing. I want to also commend Ranking Member Whitfield, who is not yet in attendance, for his efforts.

To my knowledge, this is the first congressional hearing into the safety and security of our Nation's bio-laboratories. It is a matter that deserves attention and I believe that it is timely to take it up at this point in time.

Today we mark 6 years ago to the day that the Center for Disease Control, the director of the Center for Disease Control, learned that lab tests confirmed that a patient dying a South Florida hospital was infected with anthrax. As it turned out, this was the first evidence in only a few weeks after 9/11. Our Nation, including the Nation's Capitol, faced a series of bioterrorism attacks using weapons-grade anthrax that was delivered through the mail. Consequently, five people died. That case, to this day, remains unsolved. In the wake of the anthrax attacks, the public and the Congress were astonished to learn that the Federal Government did not know how many U.S. labs handled anthrax nor could the Federal Government identify every laboratory in the country with access to the Ames strain of weaponized anthrax that had been used in the attacks. Congress responded by passing the Bioterrorism Act in 2002, which originated, if I recall correctly, in this committee. It established a regulatory system at the Centers for Disease Control over the possession, use and transfer of select agents and toxins. We also dramatically increased spending for the building, expanding laboratories that research deadly germs and toxins.

These kinds of facilities are known as biosafety level 3 and 4 laboratories. They deal in highly infectious viruses and other biological agents. The critical part of what they do, however, must be to protect the public and their own workers from the inherent dangers involved in researching the very things that they research. Strict safety rules and guidelines must be required to protect against leaks, losses, are thefts of these deadly materials.

This hearing explores several questions. Has a Bioterrorism Act helped improved Federal oversight of select agents? Are there oversight gaps? Is the expansion to research laboratories an unmitigated good or does it pose serious risk? And how well do we manage risk? There are serious reasons to be worried. Records obtained by the committee from the CDC revealed more than 100 acts in missing shipments in 2003. Fortunately, as far as we know, no deaths have been reported and it does not seem that the public has been at risk so far. A very serious biosafety incident has occurred at my alma mater, Texas A&M University. We have the president of Texas A&M here today to testify about what happened there and what Texas A&M has done to make sure that that does not happen again.

While we are examining the possible gaps in the Federal and institutional oversight of biosafety, we should also realize that the work performed in these high-risk laboratories is critical to our Nation's defense and health. Much has been made about the secrecy surrounding the bio-laboratories but it hardly seems surprising that the world of bioterrorism research is also a world steeped in secrecy. We might need this secrecy for our own protection but it can also let bad habits go unnoticed and unchallenged until a crisis exposes them.

We have seen that happen over and over again at our weapons laboratory at Los Alamos. Last year this subcommittee had to probe to learn that at the National Institutes of Health there was no central inventory of human tissue samples nor any systematic collection of data about them. We learned about that particular problem within the NIH only after the system was abused for personal gain. We also learned in the last several years how some Government scientists have been earning outside income by consulting for drug companies. We have found that a few have operated completely outside of the NIH approval and disclosure rules.

Secrecy does not seem to nurture the truth sometimes, so the fact that biosafety rules have been bent and lab safety breaches have been concealed somehow should not come to us as a complete surprise.

We are going to hear from several distinguished witnesses about the regulatory and oversight system of these laboratories. I want to particularly welcome the acting president of Texas A&M, Mr. Eddie Joe Davis. He is a personal friend of mine. He has assured me that A&M is doing everything possible to correct the problem and make sure it does not happen again. And I will assure this committee, as a past chairman of this subcommittee and a past chairman of the full committee, that if we know of a problem at Texas A&M, I will guarantee I will help correct it and I will do whatever it takes, including calling the Governor, the chairman of the Board of Regents, to make sure if the changes need to be made, they will be made. Texas A&M will be a model of how to do things right. Not that they have not been in the past but they sure will be in the present and the future in terms of this issue. You have my personal guarantee of that, Mr. Chairman.

With that I yield back to the committee and look forward to hearing of the witnesses today.

Mr. STUPAK. I thank the ranking member. Members will be moving in and out of this hearing as we have another hearing upstairs on Environment and Hazardous Materials. I guess that is an appropriate subcommittee for subject of today's hearing here.

Ms. DeGette, opening statement please?

Ms. DEGETTE. Thank you, Mr. Chairman. I would like to associate myself with your opening statement and waive my opening statement in favor of more time for questions.

Mr. STUPAK. Very good. Mr. Green?

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing. I appreciate you mentioning our subcommittee hearing upstairs. There are so many of us who are also members of that and so we will be coming and going all day, along with votes on the House floor.

But I particularly appreciate you holding this hearing on the growth of biosafety labs and the inherent safety risks we must work to mitigate.

For most of us here today, the dangers associated with bioagents are all too real as we served in this capitol complex in 2001. Several of our colleagues were targets of anthrax attacks. That attack shed tremendous light on our lack of capacity to research these agents for their health risk and find cures for the most dangerous of them.

Today, approximately 6 years later, we are charged with determining whether that capacity was increased too quickly without appropriate regulatory guidelines and safeguards. We will hear a lot today about the incidents at Texas A&M, BSL–3 lab. There is no question that the incidents have cast a dark shadow on Texas A&M select agent research program.

It appears that the proper procedure are either unknown or blatantly ignored and the university has taken full responsibility by firing the individuals who acted irresponsibly and putting the full weight of the university behind resolving the remaining issues.

I am pleased that Dr. Davis has agreed to testify before the committee today to help us learn about the A&M experience and identify any Federal oversight gaps that need to be addressed by regulation or statute.

There are several basic concerns we must address such as the fact that we do not even know how many biosafety labs are operating in our country. We know there are currently 15 BSL–4 labs either operational or under construction, that these labs handle the most deadly agents for which there is no treatment currently available. We know that there are 400 BSL–3 labs registered with the Centers for Disease Control, yet the only factor that triggers the requirement to register with the CDC seems to be the use of select agents and the official list of select agents is not continuously updated. We seem to have no clue about how many other labs there are working on agents that may not appear on that list yet are undeniably dangerous. I have every confidence this hearing will be effective in routing out many of the other regulatory issues that are facing our biological research laboratories. In our quest to fix many of the problems, however, I hope we will not lose sight of the need for this research being conducted in our country.

I am proud to have much of this research being conducted in my own backyard at UTMB, University of Texas Medical Branch in Galveston. I recently visited the construction site of UTMB's Galveston National Lab, which is one of only two national biocontainment laboratories in this country. The research at the Galveston National Lab will be conducted to develop therapies and vaccines and tests for diseases like West Nile Virus, Ebola virus and drug resistant TB, which I've had legislation on.

As a nation, we need the work to be performed in our country. During my visit to UTMB in May I learned first-hand about the measures UTMB is taking to ensure that the lab is built with every contingency in mind. I have also learned about the competence of training program that UTMB has put in place. Frankly, many of the incidents we will hear about today could have been avoided had appropriate and thorough training of research and lab employees taken place.

I plan to focus a good portion of my questions on the safety aspect of the issue, not only because there seems to be a universal need facing biosafety labs but I also have a mild personal interest in it since my daughter is currently in her second year of fellowship in infectious disease at UTMB. It is entirely possible she will work on some of the research conducted in select agents either in the currently operational BSL–4 or in the Galveston National Lab when it opens next summer. As a parent to that research, I want to make sure that these biosafety labs adhere to the highest safety training standards. And it is a source of personal comfort that UTMB has placed such an emphasis on that safety training. Given the growth of these labs nationwide, I think we need to step up our safety training efforts nationwide and my office will begin to draft legislation on this important issue.

And I appreciate the witnesses here today and the chairman for calling this hearing because our Oversight and Investigation Subcommittee does the investigation, then we have to go from there to draft legislation. And thank you, again, Mr. Chairman. I yield back my time.

Mr. STUPAK. Thank you, Mr. Green. Mr. Burgess, opening statement please.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman. Mr. Chairman, I want to assure you that I do not have duties in the other subcommittee so I will be with you all day. I did not want you to feel in danger or abandoned.

Mr. Chairman, thank you for holding the hearing today. I am grateful that we are investigating this. We are in the 21st century and we have come so far from 20th century problems, 20th century difficulties and now providing for our common defense surely includes homeland security and protecting our homeland against the threat of biological attack.

Recent years we have seen Hurricane Katrina, we have seen SARS, we have seen threats of bird flu. So natural disasters come into that list as well. We have got to have the guidelines in place. We have got to have guidelines in our labs, our streets to ensure that the very situations we are trying to protect ourselves against do not foster the environment that could be ripe for the type of biological accident or catastrophe that we all fear.

Mr. Chairman, you are right, the labs are proliferated. That is appropriate because of the 21st century threat. Our regulation remains mired in the last century. There is a plethora of agencies but they are beset by a lack of communication, which is typical of the stove piping that frequently occurs within Federal agencies. And I hope that our committee will put itself to the task of eliminating those barriers.

The truth is, the Federal Government only regulates a specific list of select agents but this list does not seem to be updated with sufficient frequency and, in fact, does not include some of the most deadly and contagious pathogens including the viruses responsible for severe adult respiratory syndrome or SARS. I cannot help but wonder, Mr. Chairman, if we are doing enough to keep this list updated to ensure that our scientists and our private citizens are protected.

I know this is supposed to be the first in a series of hearings on this issue and I ask that we specifically look into whether or not the list is updated, how it is updated and if it is done in a most timely fashion.

Now, our committee has an important responsibility to the American public and over the years I am grateful for the active and aggressive oversight that we have had in many of our labs in the country. As terrorism becomes more and more sophisticated and global activities seem to make the world a smaller and smaller place, we must continue to implement and maintain comprehensive measures for our safety.

Today's hearing brings further light to serious and ongoing transit laboratories across the country. When labs do not take adequate care and caution, they literally put some of the brightest minds of the country in danger. Part of the responsibility falls on the Federal Government due to the ambiguity regarding the regulations and the guidelines that labs must follow.

We, as members of this committee, have a duty and responsibility to the citizens of the country, to the scientists of the country, to resolve any ambiguities that currently exist within the Federal regulations so that the biosafety in all labs can be assured. The sad reality is that while the security breaches that have recently been documented in the newspapers, while they are serious, ultimately they could have been catastrophic had the right conditions prevailed at the time that those breaches occurred.

But having said all that, I do want to join my Texas colleagues in welcoming the president of one of the premier research facilities in the United States, which happens to be in one of the premier States in the United States, the State of Texas. So Texas A&M president, Dr. Ed Davis, welcome to our committee. Of course, A&M has produced some of the greatest thinking minds of this century, including our ranking member, Mr. Barton. Unfortunately, there has also been some controversy and today they are not going to just be talking about the football team record.

Dr. Davis, thank you for being here today and we look forward to hearing your discussion of exactly what happened in college station. Hopefully, you can give us some guidance on what we should do at our level to resolve the ambiguity and allow your scientists to have the tools in place to provide the safety that they need to conduct their research and ultimately protect the American people.

I would also like to briefly mention, as did my colleague, Mr. Green, the issue of training at the University of Texas Medical Branch in Galveston. They have been a leader in this, responding to a need and developing a formal training center for laboratory personnel. They are receiving Federal dollars through the Department of Defense appropriations bill. Just make a note to the Majority that we do need to vote on a conference report on the Department of Defense appropriations bill with all haste and that that should not be encumbered with other issues and I would encourage you to talk to your leadership so that we can get that done and this great lab in Mr. Green's district can go forward and provide the training that the scientists need. And they are going to work in conjunction with the Center for Disease Control and the National Institute of Health.

Again, Mr. Chairman, I thank you for holding this important hearing. I know we have got a lot of issues to get to today, so I want to be generous to you and I will yield back the balance of my time.

Mr. STUPAK. Thank you for yielding back 35 seconds. Next, go to Mr. Inslee for an opening statement. Please, sir?

Mr. INSLEE. I will waive my opening. Thank you, Mr. Chairman.

Mr. STUPAK. Mrs. Blackburn, opening statement?

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman. I appreciate the hearing and I will also, since my late father-in-law was a Texas Aggie, I will express my welcome to Mr. Hammond also and to any of the other Aggies that are in the audience.

I am delighted that we are having this hearing today. The hearing focuses on facilities that conduct research on specific infectious diseases, term-select agents. The labs that conduct the research on these select agents are classified as either a biosafety level 3 or 4. Now, in Tennessee, at the University of Tennessee, there are a couple of different labs. One is in Memphis and one is in Oak Ridge. The UT Health Science Center in Memphis is currently constructing a new regional BSL–3 biocontainment lab but we are pleased with that facility and pleased with the progress that they have made on some of their biotechnology and the research that goes with that. This is something when I was in the State senate in Tennessee. I spent a good bit of time trying to help get off the ground helping start the biotechnology association and the task force that help feed the energy into that when I was in the State senate. We know that these facilities are working with materials that can potentially cause serious harm to humans and to animals with some of the pathogens having no known cure. In today's world, the threat of terrorism, as my good colleague has mentioned, is present. Not only could terrorists potentially use one of the pathogens to harm the public, there is also the possibility that those wishing America harm could genetically alter these pathogens to form a new strain with no known cure.

And while I understand that the research is clearly needed, we must also focus on the safety of those performing the research, as well as the communities in which these labs and facilities are located. I think we have all expressed concern with the way the counting is done and knowing how many of these are actually available. We know that the NIH said there was 277 in 2005 and today the number is estimated to be around 400. I will let go also one of the things that my colleague was mentioning. The lack of communication between the agencies. When you look at the FDA, the CDC and the NIH, Mr. Chairman, we continue to hear, whether it is in health sub or here, the inter-agency, as well as the intra-agency communication and collaboration and share of information seems to not be what we would like for it to be, especially when we are looking at something as delicate and as necessary as the type of research we are talking about and I hope that we have the opportunity to address some of that today.

I do want to welcome our witnesses today. As I said, especially any Aggies who are before us, I will join in welcoming them. I also look forward to hearing and engaging in the Q and A. And, Mr. Chairman, I yield back my time.

Mr. STUPAK. I thank the gentlelady for her opening statement. That concludes the opening statements. Before we begin with testimony, I would like to recognize our colleague, Chet Edwards, who is here. Chet has Texas A&M in his district and I know he has talked to me and others about this issue. So welcome, Chet. Seeing no other members, we will move forward to our first panel of witnesses.

We have Dr. Keith Rhodes, Chief Technologist, Government Accountability Office, Center for Technology and Engineering. And with Dr. Rhodes is Dr. Sharma, who is GAO's Assistant Director of Applied Research and Methods.

It is the policy of the subcommittee to take all testimony under oath. Please be advised that witnesses have the right under the rules of the House to be advised by counsel during their testimony. Do either of you gentlemen wished to be represented by counsel? Mr. Rhodes? Dr. Sharma? No. OK. Witnesses indicated they do not, therefore, I will ask you to rise, raise your right hand, take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. You are now under oath. Dr. Rhodes, are you going to start with your opening statement please?

STATEMENT OF KEITH RHODES, CHIEF TECHNOLOGIST, CENTER FOR TECHNOLOGY AND ENGINEERING, U.S. GOVERNMENT ACCOUNTABILITY OFFICE; ACCOMPANIED BY SUSHIL K. SHARMA, ASSISTANT DIRECTOR, APPLIED RESEARCH AND METHODS, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. RHODES. Thank you, Mr. Chairman. Mr. Chairman, members of the subcommittee, my colleague, Dr. Sharma, and I are pleased to be here today to discuss our preliminary findings on the oversight of the expansion in the United States of biosafety level 3 and biosafety level 4 labs, also known as high-containment labs. This expansion is, in part, a response to the global spread of emerging infectious diseases and the threat of bioterrorism. As you know, BSL–3 and 4 labs often contain the most dangerous infectious disease agents like Ebola, small pox and avian influenza.

Although high-containment labs are designed to promote the safety of researchers and the public, accidents and security breaches have occurred in the past and they will occur in the future. Experts tell us that most accidents occur due to human error, which cannot be completely eliminated. In addition, these labs can be used by terrorists or people with malicious intent to acquire or develop harmful biological agents, posing a serious threat to our national security and public health.

The intentional dissemination of anthrax in the U.S. mail highlighted major gaps in our civilian capacity to respond to a biological attack. One such gap noted by the National Institute of Allergy and Infectious Diseases was the shortage of high-containment lab capacity available to conduct research for medical countermeasures. To address this concern, the administration and Congress responded by providing increased funding for biodefense research and for additional BSL 3 and BSL 4 labs in the private sector, especially in university settings.

As a result, concerns have been raised about the adequacy of oversight of these labs because the deliberate or accidental release of biological agents can have disastrous consequences, such as exposing workers and the public. In addition, concerns have been raised about their safety, as well as operations. Finally, there are security concerns about the potential theft of the agents themselves. Accordingly, you asked us to address the following three questions. One: Is there an expansion going on? Two: Who is in charge of this expansion? And three: What lessons can be learned from recent incidents at three high-containment labs? With regard to expansion, Mr. Chairman, as you can see on the charts, we found that a major expansion of BSL 3 and 4 labs is taking place in the United States. For example, concerning BSL–4 labs, which handle the most dangerous agents, the number of these labs has increased from five before the terrorist attacks of 2001 to 15, including at least one in planning. With regard to BSL–3 labs, no one knows how many there are but the number is surely in the thousands. In the past, the most dangerous of these types of labs, that is the BSL–4 labs, were largely in Federal hands. But since 2001, the expansion is taking place across many sectors, Federal, State, academic and private and across most of the United States. While information on expansion is available about high-containment labs that are one, registered with the select agent program and two, federally funded, much less is known about the expansion of labs outside the select agent program, as well as the non-federally funded labs including their location, activities and ownership.

With regard to who is in charge of this expansion, Mr. Chairman, we found no single Federal agency has the mission and, therefore, is accountable for tracking the number of all BSL–3 and 4 labs within the United States. Although several agencies have a need to know the number and location of these labs to support their missions, no agency knows how many such labs there are in the United States or their locations. Therefore, no Federal agency is responsible for determining the aggregate risks associated with the expansion of these labs. Since there is a baseline risk associated with any high-containment lab, the aggregate risk associated with this expansion will increase as their numbers increase. Importantly, the safety and security risks will be greater for new labs with less experience.

Finally, from the three recent incidents that you asked us to examine, one: the failure to report to CDC exposures to select agents by Texas A&M University, two: the power outage at CDC's new BSL–4 lab, and three: the most recent release of the foot-and-mouth disease virus at Pirbright in the United Kingdom. We have identified six lessons that can be learned. These lessons highlight the importance of one: identifying and overcoming barriers to reporting in order to enhance biosafety through shared learning from mistakes and to assure the public that accidents are examined and contained. Two, training lab staff in general biosafety, as well as in specific agents being used in the labs to ensure maximum protection. Three, developing mechanisms for informing medical providers about all the agents that lab staff work with to ensure quick diagnosis and effective treatment. Four, addressing confusion over the definition of exposure to aid in the consistency of reporting. Five, ensuring that BSL–4 lab safety and security measures are commensurate with the level of risk these labs present. And six, maintaining high-containment labs to ensure integrity of physical infrastructure over time.

In summary, the expansion of BSL–3 and 4 labs is indeed taking place in the United States and it is proceeding in a decentralized fashion. While some expansion may be justified, unwarranted expansion without adequate oversight is proliferation, not expansion. Since the full extent of the expansion is not known, it is unclear how the Federal Government can ensure that sufficient but not superfluous capacity, bringing with it additional unnecessary risk is being created.

In conclusion, Mr. Chairman, the limited Federal oversight that does exist for high-containment labs is fragmented among different Federal agencies and for the most part, relies on self-policing.

As you have said in your opening statement, the inherent weaknesses of an oversight system based on self-policing are highlighted by the Texas A&M University case. While CDC inspected the labs at Texas A&M in February 2006, as part of its routine inspection, its inspectors failed to identify three items. One, a worker became exposed and ill. Two, unauthorized experiments were being conducted and unauthorized individuals were entering the labs. And three, both the agents and infected animals were missing. It was not until a public advocacy group learned of the *Brucella* incident and according to this group, applied pressure by demanding records about the incident, that the university reported this incident to the CDC. This report prompted the subsequent in-depth investigations by the CDC. This incident is raising serious concerns about, one, how well the agency polices select agent research being conducted in over 400 high-containment labs registered under the select agent program located at various universities around the country and, two, whether the safety of the public is compromised. Moreover, if similar safety breaches are occurring at other labs, they are not being reported nor is CDC finding them.

I want to leave you with this thought. Since the labs are largely overseeing themselves at this point, it is not the regulators but only the operators of these labs who can tell you whether the three recent incidents are the tip of the iceberg or the iceberg itself.

Mr. Chairman, this concludes my prepared remarks. Dr. Sharma and I stand ready to answer any questions you or members of the subcommittee may have.

[The prepared statement of Mr. Rhodes follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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HIGH-CONTAINMENT BIOSAFETY LABORATORIES

Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States

Statement of Keith Rhodes, Chief Technologist
Center for Technology and Engineering
Applied Research and Methods

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Highlights

Highlights of GAO-08-108T, a testimony before the Subcommittee on Oversight and Investigation, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

In response to the global spread of emerging infectious diseases and the threat of bioterrorism, high-containment biosafety laboratories (BSL)–specifically biosafety level (BSL)-3 and BSL-4–have been proliferating in the United States. These labs—classified by the type of agents used and the risk posed to personnel, the environment, and the community—often contain the most dangerous infectious disease agents, such as Ebola, smallpox, and avian influenza. This testimony addresses (1) the extent to which there has been a proliferation of BSL-3 and BSL-4 labs, (2) federal agencies' responsibility for tracking this proliferation and determining the associated risks, and (3) the lessons that can be learned from recent incidents at three high-containment biosafety labs. To address these objectives, GAO asked 12 federal agencies involved with high-containment labs about their missions and whether they tracked the number of labs overall. GAO also reviewed documents from these agencies, such as pertinent legislation, regulation, and guidance. Finally, GAO interviewed academic experts in microbiological research.

To view the full product, including the scope and methodology, click on GAO-08-108T. For more information, contact Keith Rhodes at (202) 512-6412 or rhodesk@gao.gov.

October 4, 2007

HIGH-CONTAINMENT BIOSAFETY LABORATORIES

Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States

What GAO Found

A major proliferation of high-containment BSL-3 and BSL-4 labs is taking place in the United States, according to the literature, federal agency officials, and experts. The expansion is taking place across many sectors—federal, academic, state, and private—and all over the United States. Concerning BSL-4 labs, which handle the most dangerous agents, the number of these labs has increased from 5—before the terrorist attacks of 2001—to 15, including at least 1 in planning stage. Information on expansion is available about high-containment labs that are registered with the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture's (USDA) Select Agent Program, and that are federally funded. However, much less is known about the expansion of labs outside the Select Agent Program, as well as the nonfederally funded labs, including location, activities, and ownership.

No single federal agency, according to 12 agencies' responses to our survey, has the mission to track the overall number of BSL-3 and BSL-4 labs in the United States. Though several agencies have a need to know, no one agency knows the number and location of these labs in the United States. Consequently, no agency is responsible for determining the risks associated with the proliferation of these labs.

We identified six lessons from three recent incidents: failure to report to CDC exposures to select agents by Texas A&M University (TAMU); power outage at the CDC's new BSL-4 lab in Atlanta, Georgia; and release of foot-and-mouth disease virus at Pirbright in the United Kingdom. These lessons highlight the importance of (1) identifying and overcoming barriers to reporting in order to enhance biosafety through shared learning from mistakes and to assure the public that accidents are examined and contained; (2) training lab staff in general biosafety, as well as in specific agents being used in the labs to ensure maximum protection; (3) developing mechanisms for informing medical providers about all the agents that lab staff work with to ensure quick diagnosis and effective treatment; (4) addressing confusion over the definition of exposure to aid in the consistency of reporting; (5) ensuring that BSL-4 labs' safety and security measures are commensurate with the level of risk these labs present; and (6) maintenance of high-containment labs to ensure integrity of physical infrastructure over time.

Summary of Known BSL-4 Labs in the United States by Sector

Sector	Before 1990	1990-2000	2001-Present	Total
Federal government	2	1	6	9
Academic	0	1	3	4
State	0	0	1	1
Private	0	1	0	1
Total	**2**	**3**	**10**	**15**

Source: GAO analysis based on open source information.

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss our preliminary findings on the oversight of the expansion of high-containment biosafety level (BSL)-3 and BSL-4 laboratories (labs) in the United States. This expansion is, in part, a response to the global spread of emerging infectious diseases and the threat of bioterrorism.

BSL-3 and BSL-4 labs often contain the most dangerous infectious disease agents (for example, Ebola, smallpox, avian influenza, and severe acute respiratory syndrome [SARS]), including those for which effective vaccines or treatment may not be available. Although high-containment labs are designed to promote the safety of researchers and the public, accidents and security breaches have occurred in the past. In addition, these labs can be used by terrorists or people with malicious intent to acquire or develop harmful biological agents,[1] posing a severe national security and public health threat.

The intentional dissemination of an agent—anthrax—in the U.S. mail demonstrated the devastating effect such agents can have in the wrong hands. As a result of exposure to anthrax-tainted mail in the fall of 2001, 22 individuals contracted anthrax disease in four states—Connecticut, Florida, New Jersey, and New York—as well as in Washington, D.C. Of these 22 individuals, 5 died.

These anthrax incidents highlighted major gaps in our civilian capacity to respond to a biological attack; most noted among them, according to the National Institute of Allergy and Infectious Diseases (NIAID), was the shortage of high-containment lab capacity available to conduct research leading to the development of medical countermeasures.[2] To address this concern, the Administration and Congress responded by providing increased funding for biodefense research and for additional BSL-3 and BSL-4 labs in the private sector, especially in university settings.

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[1] Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa) or infectious substance or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

[2] National Institute of Allergy and Infectious Diseases, *Survey for Determining the Location, Capacity, and Status of Existing and Operating BSL-3 Laboratories within the United States* (Washington, D.C., June 2, 2005).

However, concerns have been raised about the oversight of these labs because the deliberate or accidental release of biological agents can have disastrous consequences, such as exposing workers and the public. In addition, as the number of BSL-3 and BSL-4 labs has been increasing, concerns have also been raised about their safety, as well as operations. Finally, there are security concerns about the potential theft of the material itself. Accordingly, you asked us to address the following three questions:

1. To what extent, and in what areas, has there been an expansion in the number of high-containment labs in the United States?
2. Which federal agency is responsible for tracking the expansion of high-containment labs and determining the associated aggregate risks?
3. What lessons can be learned from recent incidents at three high-containment labs?

To answer these questions, we interviewed officials from several federal agencies, as well as experts; reviewed literature; conducted site visits; and surveyed 12 federal agencies. We conducted our work from August 2006 through September 2007 in accordance with generally accepted government auditing standards (see appendix I for our scope and methodology).

Background

Since September 11, 2001, there has been an increase in the funding for research in biomedicine. This increase is intended to develop effective medical countermeasures, against emerging infectious diseases and biological agents, which can only be performed safely in BSL-3 and BSL-4 labs. A large part of this funding has been used to construct additional high-containment BSL-3 and BSL-4 labs.

BSL-3 and BSL-4 Labs

The BSL labs are classified by the type of agents used and the risk posed to personnel, the environment, and the community by those agents. The Department of Health and Human Services's (HHS) Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines specify four biosafety levels,[3] with BSL-4 being the highest. The levels include combinations of laboratory practices and techniques, safety equipment, and facilities that are recommended for labs that conduct research on potentially dangerous agents and toxins. These labs are to be designed, constructed, and operated in a manner to (1) prevent accidental release of infectious or hazardous agents within the laboratory and (2) protect lab workers and the environment external to the lab, including the community, from exposure to the agents.

Work in BSL-3 labs involves agents that may cause serious and potentially lethal infection. In some cases, there are vaccines or effective treatments available. Types of agents that are typically handled in BSL-3 labs include, for example, anthrax, West Nile Virus, Q fever, tularemia, and avian flu. Work in BSL-4 labs involves the most dangerous agents for which there are no effective vaccines or treatments available. Types of agents that are typically handled in BSL-4 labs include, for example, Ebola, hemorrhagic fevers, and smallpox.[4]

Federal Agencies and BSL-3 and BSL-4 Labs

Many different federal agencies have some connection with BSL-3 and BSL-4 labs in the United States. These agencies are involved with these labs in various capacities, including as users, owners, regulators, and funding sources. For example, the Centers for Disease Control and Prevention (CDC) has its own high-containment labs and regulates that portion of labs working with select agents and toxins that represent a risk to human health and safety. Similarly, the U.S. Department of Agriculture (USDA) has its own labs and regulates labs working with select agents and toxins posing a risk to animal and plant health. The NIAID has its own labs and is a major funding source for construction and research involving high-containment labs. The National Institutes of Health (NIH) both funds research requiring high containment and provides guidance that is widely used to govern many of the activities in high-containment labs. The Food and Drug Administration (FDA) has its own labs and regulates manufacturing of biological products, some of which require high-containment labs. The Department of Commerce (DOC) regulates the export of agents and equipment that have both military and civilian uses, which are often found in high-containment labs. The Department of Defense (DOD) has its own labs and funds research requiring high-containment labs. The Department of Labor's (DOL) Occupational Safety and Health Administration (OSHA) regulates some activities within high-containment labs, as well as general safety in most high-containment labs. The Department of State (DOS) regulates the export of agents and equipment that are specifically designed for military use from defense-related high-containment labs and maintains a listing of some high-containment labs, as part of the U.S. commitments under the Biological and Toxin Weapons Convention (BWC). The Department of Justice's (DOJ) Federal Bureau of Investigation (FBI) uses high-containment labs when their forensic work involves dangerous biological agents. The Department of Homeland Security (DHS) has its own labs and funds a variety of research requiring high-containment labs. The Department of Energy (DOE) has several BSL-3 labs doing research to develop detection and response systems to improve preparedness for biological attack. The Department of Interior (DOI) has its own BSL-3 labs for work with infectious animal diseases. The Department of Veterans Affairs (VA) has research and clinical BSL-3 labs for its work with veterans. The Environmental Protection Agency (EPA) has its own labs and also coordinates use of various academic, state, and commercial high-containment labs nationwide, as part of its emergency response mission.

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[3] Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (Washington, DC., 2007).

[4] Smallpox is only handled at the CDC labs in Atlanta.

Pertinent Laws and Guidance

The pertinent laws and guidance include the following (see appendix II for pertinent regulations):

Pertinent Laws

The Antiterrorism and Effective Death Penalty Act of 1996 includes provisions to regulate the transfer, between laboratories, of certain biological agents and toxins and requires the Secretary of HHS to implement these provisions. As part of the implementation of this act, the first list of regulated biological agents was created. This became known as the select agent list.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 revised and expanded the Select Agent Program. Among other requirements, the new law (1) revised the list of agents deemed "select agents," which possess the "potential to pose a severe threat" to public health and safety, to animal or plant health, or to animal or plant products; (2) directed the Secretaries of HHS and Agriculture to biennially review and publish the select agent list, making revisions as appropriate to protect the public; (3) required all facilities possessing select agents to register with the Secretary of HHS, Agriculture, or both, not just those facilities sending or receiving select agents; (4) restricted access to biological agents and toxins by persons who do not have a legitimate need and who are considered a risk by federal law enforcement and intelligence officials; (5) required transfer registrations to include information regarding the characterization of agents and toxins to facilitate their identification, including their source; (6) required the creation of a national database with information on all facilities and persons possessing, using, or transferring select agents; and (7) required the Secretaries of HHS and Agriculture to impose more detailed and different levels of security for different select agents, based on their assessed level of threat to the public.

Pertinent Guidance

Pertinent guidance includes NIH and CDC BMBL guidance, as well as NIH guidelines.

NIH and CDC BMBL Guidance

The NIH and CDC prepared the BMBL as a guidance document for working with particular select agents. According to the BMBL guidelines, (1) BSL-1 laboratories house agents and toxins that do not consistently cause disease in healthy adult humans; (2) BSL-2 laboratories are capable of housing agents and toxins that are spread through puncture, absorption through mucous membranes, or ingestion of infectious materials; (3) BSL-3 laboratories are capable of housing agents and toxins that have a potential for aerosol transmission and that may cause serious and potentially lethal infection; (4) BSL-4 laboratories are capable of housing agents and toxins that pose a high individual risk of life-threatening disease, which may be aerosol transmitted and for which there is no available vaccine or therapy.

The BMBL states that (1) biosafety procedures must be incorporated into the laboratory's standard operating procedures or biosafety manual; (2) personnel must be advised of special hazards and are required to read and follow instructions on practices and procedures; and (3) personnel must receive training on the potential hazards associated with the work involved and the necessary precautions to prevent exposure. Further, the BMBL contains guidelines for laboratory security and emergency response, such as controlling access to areas where select agents are used or stored. The BMBL also states that a plan must be in place for informing police, fire, and other emergency responders as to the type of biological materials in use in the laboratory areas.

NIH Guidelines for Research Involving Recombinant DNA Molecules

Much of the work in BSL-3 and BSL-4 labs in the United States involves recombinant DNA (rDNA), and the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH rDNA Guidelines) set the standards and procedures for research involving rDNA. Institutions must follow these guidelines when they receive NIH funding for this type of research. The guidelines include the requirement to establish an institutional biosafety committee (IBC). The IBC is responsible for (1) reviewing rDNA research conducted at or sponsored by the institution for compliance with the NIH rDNA Guidelines and (2) approving those research projects that are found to conform with the NIH rDNA Guidelines. IBCs also periodically review ongoing rDNA research to ensure continued compliance with the NIH rDNA Guidelines.

The Select Agent Program

The CDC is responsible for the registration and oversight of laboratories that possess, use, or transfer select agents and toxins that could pose a threat to human health. USDA is responsible for the registration and oversight of laboratories that possess, use, or transfer select agents and toxins that could pose a threat to animal or plant health or animal or plant products. Some select agents, such as anthrax, pose a threat to both human and animal health and are regulated by both agencies (see appendix III for the list of select agents and toxins).

The select agent regulations require registration for U.S.-based research institutions, government agencies, universities, manufacturers, and other entities that possess, use, or transfer select agents. Registration is for 3 years. As part of the registration process, facilities must demonstrate in their applications that they meet the recommendations delineated in the BMBL for working with particular select agents. Such requirements include having proper laboratory and personal protective equipment, precautionary signage, and ventilation; controlled access; and biosafety operations manuals. Facilities must also describe the laboratory procedures that will be used, provide a laboratory floor plan showing where the select agent will be handled and stored, and describe how access will be limited to authorized personnel.

In addition, facilities must describe the objectives of the work that requires the select agent. Each facility must identify a responsible facility official who is authorized to transfer and receive select agents on behalf of the facility. Individuals making false, fictitious, or fraudulent statements on registration forms may be punished, under the False Statements Act, by a fine of up to $250,000, imprisonment up to 5 years, or both. Violations by organizations are punishable by a fine of up to $500,000 per violation. To ensure compliance with these requirements, the program established a goal of inspecting these facilities once during the 3-year registration period. Facilities may be inspected before and after registration, but there is no requirement that inspections be performed.

Results in Brief

A major expansion of high-containment biosafety labs (BSL-3 and BSL-4) is taking place in the United States, according to the literature, federal agency officials, and experts. Concerning BSL-4 labs, which handle the most dangerous agents, the number of these labs has increased from 5—before the terrorist attacks of 2001—to 15, including at least 1 in the planning stage. The expansion is taking place across many sectors—federal, state, academic, and private[5]—and across most of the United States. Information on expansion is available about high-containment labs that are (1) registered with the CDC-USDA Select Agent Program and (2) federally funded. However, much less is known about the expansion of labs outside the Select Agent Program as well as the nonfederally funded labs, including location, activities, and ownership.

No single federal agency has the mission and, therefore, is accountable for tracking the number of all BSL-3 and BSL-4 labs within the United States. Moreover, although several agencies have a need to know the number and location of these labs to support their missions, no agency knows how many such labs there are in the United States or their locations, according to agencies' responses to our survey. Therefore, no agency is responsible for determining the aggregate risks associated with the expansion of these labs. According to the experts, there is a baseline risk associated with any high-containment lab, attributable to human errors. With this expansion, the risk will increase. However, the associated safety and security risks will be greater for new labs with less experience.

We identified six lessons from three recent incidents: failure to report to CDC exposures to select agents by Texas A&M University (TAMU); power outage at CDC's new BSL-4 lab in Atlanta, Georgia; and a release of foot-and-mouth disease virus at Pirbright in the United Kingdom (U.K.). These lessons highlight the importance of (1) identifying and overcoming barriers to reporting in order to enhance biosafety through shared learning from mistakes and to assure the public that accidents are examined and contained; (2) training lab staff in general biosafety, as well as in specific agents being used in the labs to ensure maximum protection; (3) developing mechanisms for informing medical providers about all the agents that lab staff work with to ensure quick diagnosis and effective treatment; (4) addressing confusion over the definition of exposure to aid in the consistency of reporting; (5) ensuring that BSL-4 labs' safety and security measures are commensurate with the level of risk these labs present; and (6) maintenance of high-containment labs to ensure integrity of physical infrastructure over time.

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[5] Private sector labs include commercial labs.

Expansion of BSL-3 and BSL-4 Labs Is Taking Place across Many Sectors and All over the United States

An expansion in the number of BSL-3 and BSL-4 labs is taking place across most of the United States,[6] according to the literature, federal agency officials, and experts. Most federal officials and experts believe that the number of BSL-4 labs in the United States is generally known. But the number of BSL-3 labs is unknown. Information on expansion is available about high-containment labs that are (1) registered with the CDC-USDA's Select Agent Program, and (2) federally funded. However, much less is known about the expansion of labs outside the Select Agent Program and the nonfederally funded labs, including location, activities, and ownership. For both BLS-3 and BSL-4, the expansion is taking place across many sectors—federal, state, academic, and private—and all over the United States.

An Expansion of BSL-3 and BSL-4 Labs Is Taking Place in All Sectors in the United States

For most of the last 50 years, there were only two sites with BSL-4 labs in the United States. These were federal labs at the U.S. Army's Research Institute for Infectious Diseases (USAMRIID) in Fort Detrick, Maryland, and at the CDC in Atlanta, Georgia. Between 1990 and 2000, three new BSL-4 labs were built: a BSL-4 lab at Georgia State University in Atlanta—the first BSL-4 lab in a university setting; a small BSL-4 lab on the NIH campus in Bethesda, Maryland;[7] and a privately funded BSL-4 lab in San Antonio, Texas. Since the terror attacks of 2001, nine new facilities and one major remodeling effort containing BSL-4 space will either be operational, in construction, or in planning by this year's end. The number of BSL-4 laboratories has increased from 5, before 2001, to 15, including at least 1 in planning.

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[6] There are a number of methodological issues associated with determining the overall number of BSL-3 and BSL-4 labs. In our discussion with federal agency officials, experts, and review of the literature, we found that the total number depended upon how you ask the question. Most often data were available on the number of facilities or sites that contained a BSL-3 or BSL-4 lab. The precise number of independent rooms within those facilities qualifying as BSL-3 or BSL-4 is not generally specified. Some facilities contain more than one actual lab. For example, while CDC has two facilities with BSL-4 capacity, one of the facilities actually contains within it two separate BSL-4 labs, while the other has four separate BSL-4 labs. These officials and experts also told us that counting the number of labs is problematic because the definition of the term "lab" varies. A more meaningful measure is determining the net square footage of working BSL-4 space. However, this information is often not available.

Moreover, expansion is taking place across all sectors. Before 1990, all BSL-4 labs were federal labs—either at USAMRIID or at the CDC. Today, while expansion is taking place within the federal sector as well—there are seven new federal facilities recently built, currently under construction, or planned, which have one or more BSL-4 labs—there are also BSL-4 labs at universities, as part of state response, and in the private sector. (See table 1 for expansion in BSL-4 labs by sector.)

Table 1: Summary of Known BSL-4 Labs in the United States, by Sector

Sector	Before 1990	1990-2000	2001-Present	Total
Federal government	2	1	6	**9**
Academic	0	1	3	**4**
State	0	0	1	**1**
Private	0	1	0	**1**
Total	**2**	**3**	**10**	**15**

Source: GAO analysis based on open source information.

Note: These numbers represent the lower bound of the number of BSL-4 labs. Within each of these facilities, there may be several independent rooms designated as work areas, each at BSL-4 level.

While the number is difficult to quantify, many more BSL-3 labs are thought to exist compared with BSL-4 labs. Many lab owners—when building new labs or upgrading existing ones—are building to meet BSL-3 level containment, often anticipating future work, even though they intend for some time to operate at the BSL-2 level with BSL-2 recommended agents. In addition, much biodefense work, for example, involves aerosolization of agents for challenge studies, and most of this type of activity is often recommended for containment at the BSL-3 level.

The expansion of BSL-3 labs is in all sectors. However, the only definitive data available are on labs registered with the CDC-USDA Select Agent

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[7] This is lab was built as a BSL-4 but currently operates as an enhanced BSL-3.

Program. Within that program, two-thirds of registered BSL-3 labs are outside the federal sector (see table 2).

Table 2: BSL-3 Labs Registered with the CDC and USDA Select Agent Program, by Sector

Sector	CDC-registered labs	USDA- registered labs	Total
	Number	Number	Number
Federal	291	167	458
Academic	429	58	487
State	248	20	268
Private	74	69	143
Total	**1042**	**314**	**1356**

Source: GAO's analysis of CDC-USDA data.

Within the academic sector, for example, NIAID has provided funding for 13 Regional Biocontainment Laboratories (RBL) to provide regional BSL-3 capability for academic research requiring such containment. Expansion at the state level is also taking place (see table 3). According to a survey conducted by the Association of Public Health Laboratories (APHL) in August 2004, since 2001 state public health labs have used public health preparedness funding to build, expand, and enhance BSL-3 labs.[8] In 1998, for example, APHL found that 12 of 38 responding states reported having a state public health laboratory at the BSL-3 level. Today, at least 46 states have at least one state public health BSL-3 lab.

Table 3: BSL-3 Labs in the State Public Health System

Calendar year	State public health BSL-3 labs
2001	69
2002	71

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[8] Association of Public Health Laboratories, *Public Health Laboratory Issues in Brief: Bioterrorisn Capacity* (Washington D.C., April 2005).

Calendar year	State public health BSL-3 labs
2003	139

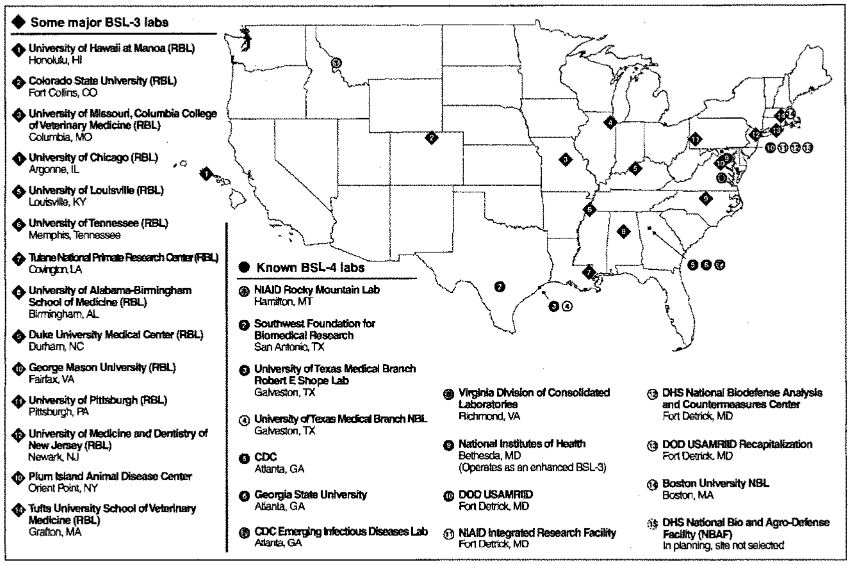
Source: Association of Public Health Laboratories, 2005.

The Expansion of BSL-3 and BSL-4 Labs Is Taking Place Generally across the United States

Expansion of BSL-3 and BSL-4 labs is starting to take place geographically as well as by sector. For example, before 1990, BSL-4 labs were clustered at either USAMRIID at Fort Detrick or at CDC. Today, there are BSL-4 labs built, under construction, or in planning in four states other than Maryland and Georgia.

The expansion of BSL-3 labs is widespread across most states. Because of the need for individual state response to bioterrorist threats, most states now have some level of BSL-3 capacity—at least for diagnostic and analytical services—in support of emergency response. In addition, within the academic research community, the RBLs being constructed by the NIAID are intended to provide regional BSL-3 laboratory capacity to support NIAID's Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE). Hence, the RBLs are distributed regionally around the country. Operational, under construction, or currently planned BSL-4 labs and some of the major BSL-3 facilities in the United States are shown in figure 1.

Figure 1: Known BSL-4 Labs and Some of the Major BSL-3 Labs in the United States



◆ Some major BSL-3 labs

1. **University of Hawaii at Manoa (RBL)** Honolulu, HI
2. **Colorado State University (RBL)** Fort Collins, CO
3. **University of Missouri, Columbia College of Veterinary Medicine (RBL)** Columbia, MO
4. **University of Chicago (RBL)** Argonne, IL
5. **University of Louisville (RBL)** Louisville, KY
6. **University of Tennessee (RBL)** Memphis, Tennessee
7. **Tulane National Primate Research Center (RBL)** Covington, LA
8. **University of Alabama-Birmingham School of Medicine (RBL)** Birmingham, AL
9. **Duke University Medical Center (RBL)** Durham, NC
10. **George Mason University (RBL)** Fairfax, VA
11. **University of Pittsburgh (RBL)** Pittsburgh, PA
12. **University of Medicine and Dentistry of New Jersey (RBL)** Newark, NJ
13. **Plum Island Animal Disease Center** Orient Point, NY
14. **Tufts University School of Veterinary Medicine (RBL)** Grafton, MA

● Known BSL-4 labs

1. **NIAID Rocky Mountain Lab** Hamilton, MT
2. **Southwest Foundation for Biomedical Research** San Antonio, TX
3. **University of Texas Medical Branch Robert E Shope Lab** Galveston, TX
4. **University of Texas Medical Branch NBL** Galveston, TX
5. **CDC** Atlanta, GA
6. **Georgia State University** Atlanta, GA
7. **CDC Emerging Infectious Diseases Lab** Atlanta, GA
8. **Virginia Division of Consolidated Laboratories** Richmond, VA
9. **National Institutes of Health** Bethesda, MD (Operates as an enhanced BSL-3)
10. **DOD USAMRIID** Fort Detrick, MD
11. **NIAID Integrated Research Facility** Fort Detrick, MD
12. **DHS National Biodefense Analysis and Countermeasures Center** Fort Detrick, MD
13. **DOD USAMRIID Recapitalization** Fort Detrick, MD
14. **Boston University NBL** Boston, MA
15. **DHS National Bio and Agro-Defense Facility (NBAF)** In planning, site not selected

◆ Major BSL-3 lab
⊙ Known BSL-4 lab is under construction
⊛ Known BSL-4 lab has been built but is not yet operational
● Known BSL-4 lab is operational
◌ Known BSL-4 lab is in planning, site not selected

Source: NIAID and open source.

No Federal Agency Has the Mission to Track High-Containment Labs in the United States

No single federal agency has the mission to track and determine the risk associated with the expansion of BSL-3 and BSL-4 labs in the United States, and no single federal agency knows how many such labs there are in the United States. Consequently, no one is responsible for determining the aggregate risks associated with the expansion of these high-containment labs.

None of the federal agencies that responded to our survey indicated that they have the mission to track and know the number of BSL-3 and BSL-4 labs within the United States (see table 4).

Table 4: Federal Agencies' Mission to Track and Know the Number of All BSL-3 and BSL-4 Labs within the United States

Agency	Mission to track	Know the number
Department of Commerce	No	No
Department of Defense	No	No
Department of Energy	No	No
Department of Health and Human Services	No	No
Department of Homeland Security	No	No
Department of Interior	No	No
Department of Justice	No	No
Department of Labor	No	No
Department of State	No	No
Department of Veterans Affairs	No	No
Environmental Protection Agency	No	No
U.S. Department of Agriculture	No	No

Source: GAO Survey of Federal Agencies Involved with BSL-3 and BSL-4 Labs, 2007.

Some federal agencies do have a narrow mission to track a subset of BSL-3 and BSL-4 labs, and they do know the number of those labs. For example, the CDC and USDA together know the number of high-containment labs working with select agents because, by federal regulation, such labs are required to register with them. But these regulations only require that the entities registering with the Select Agent Program do a risk assessment of their individual labs. No agency, therefore, has the mission to determine the aggregate risks associated with the expansion of high-containment labs that work with select agents. According to the federal agency officials, the oversight of these labs is fragmented and relies on self-policing.

While the number and location of all BSL-3 and BSL-4 labs is not known, several federal agencies indicated that they have a need to know this information in support of their agency missions. Some intelligence agencies, for example, indicated that they need to know a subset of the number and location of high-containment labs within the United States because these labs represent a capability that can be misused by terrorists or people with malicious intent.[9] Without knowledge of the number and location of the BSL-3 and BSL-4 labs, some agencies' work is made more difficult. For example, the FBI has a need to know the number and location of BSL-3 and BSL-4 labs for forensic purposes. Without this information, the FBI's work is made more difficult.

According to the experts, there is a baseline risk associated with any high-containment. With expansion, the aggregate risks will increase. However, the associated safety and security risks will be greater for new labs with less experience. In addition, high-containment labs have health risks for individual lab workers as well as the surrounding community. According to a CDC official, the risks due to accidental exposure or release can never be completely eliminated, and even labs within sophisticated biological research programs—including those most extensively regulated—have had and will continue to have safety failures. In addition, while some of the most dangerous agents are regulated under the CDC-USDA's Select Agent Program, many high-containment labs work with agents not covered under this program. Labs outside the Select Agent Program also pose risks, given that many unregulated agents can cause severe illness or even death (see appendix IV for a list of some agents, but not select agents, recommended to be worked on in high-containment labs). These labs also have associated risks because of their potential as targets for terrorism or theft from either external or internal sources. Even labs outside the Select Agent Program can pose security risks in that such labs represent a capability that can be paired with the necessary agents to become a threat. While the United States has regulations governing select agents, many nations do not have any regulations governing the transfer or possession of dangerous biological agents.

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[9] Some intelligence agencies have a mission to track and a need to know the number of all BSL-3 and BSL-4 labs or equivalent abroad. However, they do not know the total number of those labs.

Lessons Learned from Three Recent Incidents Highlight the Risks Inherent in the Expansion of High-Containment Labs

We identified six lessons from three recent incidents: failure to report to CDC exposures to select agents, in 2006, by TAMU (see appendix V); power outage at CDC's new BSL-4 lab, in 2007; and the release of foot-and-mouth disease virus, in 2007, at Pirbright, the U.K. These lessons highlight the importance of (1) identifying and overcoming barriers to reporting in order to enhance biosafety through shared learning from mistakes and to assure the public that accidents are examined and contained; (2) training lab staff in general biosafety as well as in specific agents being used in the labs to ensure maximum protection; (3) developing mechanisms for informing medical providers about all the agents that lab staff work with to ensure quick diagnosis and effective treatment; (4) addressing confusion over the definition of exposure to aid in the consistency of reporting; (5) ensuring that BSL-4 labs' safety and security measures are commensurate with the level of risk these labs present; and (6) maintenance of high-containment labs to ensure integrity of physical infrastructure over time.

Identifying and Overcoming Barriers to Reporting

While the Select Agent Program and the rDNA Guidelines have reporting requirements, institutions sometimes fail to report incidents. According to CDC, there were three specific types of incidents that TAMU officials failed to report to CDC: (1) multiple incidents of exposure, including illness; (2) specific types of experiments being conducted by researchers; and (3) missing vials and animals.

In addition, in November 2006, during our first visit to TAMU—a meeting in which all key officials who knew about these incidents were present—we asked if there had been any incident in which a lab worker was exposed to a select agent. TAMU officials did not disclose any of these incidents. Moreover, in August 2007, during our second visit, the biosafety officer said that he had conducted an investigation of the incident, in which the lab worker was exposed to *Brucella*, and wrote a report. However, the report that was provided to us was dated June 17, 2006, but discussed other incidents that had occurred in 2007, a discrepancy that TAMU failed to explain to us.[10]

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[10] The biosafety officer at TAMU told us the following: He had no training in biosafety but was an industrial hygienist by education and experience. He was asked to take on the additional duty of biosafety officer when the previous biosafety officer retired. He was also designated as an alternate responsible officer (RO) but did not know what duties he had to perform as an alternate RO.

According to the literature and discussion with federal officials and experts, accidents in labs are expected, mostly as a result of human error due to carelessness, inadequate training, or poor judgment. In the case of theft, loss, occupational exposure, or release of the select agent, the lab must immediately report certain information to CDC or USDA. However, there is a paucity of information on barriers to reporting by institutions. It has been suggested that there is a disincentive to report acquired infections and other mishaps at research institutions because of (1) negative publicity for the institution or (2) the scrutiny from a granting agency, which might result in the suspension of research or an adverse effect on future funding.[11] Further, it is generally believed that when a worker acquires an infection in the lab, it is almost always his or her fault, and neither the worker nor the lab is interested in negative publicity.

In order to enhance reporting, barriers need to be identified and targeted strategies need to be applied to remove those barriers. It is also important that these incidents be analyzed so (1) biosafety can be enhanced through shared learning from mistakes and (2) the public may be reassured that accidents are thoroughly examined and contained. One possible mechanism for analysis, discussed in the literature, is the reporting system used for aviation incidents, administered by the National Transportation Safety Board and the Federal Aviation Administration.[12] When mistakes are made, they are analyzed and learned from without being attributed to any one individual. Experts have agreed that some form of personal anonymity would encourage reporting.

Training Lab Staff in General Biosafety, as well as in Specific Agents Being Used in the Labs

Training is a key requisite for safe and secure work with dangerous agents. Moreover, it is important that this training is specific to the agent to be worked with and activities to be performed.

The lab worker at TAMU who was exposed was not authorized to work with *Brucella* but was, we were told, being escorted in the lab only to help out with the operating of the aerosolization chamber.[13] According to the select agent regulations, all staff are required to be trained in the specifics of any agent before they work with it. However, the worker did not receive training in the specifics of *Brucella*, including its characteristics, safe handling procedures, and potential health effects. While the worker was experienced in general BSL-3 procedures, her normal work regimen involved working with *Mycobacterium tuberculosis*, and her supervisor surmised that the differential potential for infection from *Brucella* was partially to blame for the exposure.[14]

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[11] High-Containment Biodefense Research Laboratories, Meeting Report and Center Recommendations, *Biosecurity and Bioterrorism*, vol. 5, 1 (New Rochelle, N.Y.: March 2007).

[12] Department of Transportation, Federal Aviation Administration, *FAA Procedures for Handling National Transportation Safety Board Recommendations* (Washington, D.C.: Federal Aviation Administration, March 22, 1995). Also see Federal Aviation Administration, *Accident and Incident Data* (Washington, D.C.: Federal Aviation Administration, Sept. 29, 2006).

In particular, the exposed lab worker was highly experienced in handling *M. tuberculosis*, an infectious agent. A lab director of a BSL-2 lab for the last 5 years, she had a PhD in medical sciences and was, by many accounts, highly competent and reliable. She had applied the procedures governing safe work with *M. tuberculosis* to the *Brucella* experiment. However, her experience with *M. tuberculosis* might have provided a false sense of security.

Had training been given in *Brucella*, the worker might have been more aware when cleaning the aerosol chamber. Typical routes of infection differ between *M. tuberculosis* and *Brucella* and normal procedures, including gowning and respiratory equipment, vary between the two agents. For example, the lab worker wore protective glasses, but they were not tight fitting. This was adequate when working with *M. tuberculosis*, but not with *Brucella*. The investigation concluded that the agent entered the lab worker through the eyes.

According to one expert who has managed high-containment labs, there are risks working alternately in BSL-2 and BSL-3 labs, with their different levels of procedures and practices. The fear is that lab workers may develop a routine with BSL-2 procedures that might be difficult to consciously break when working with the more dangerous agents and activities requiring BSL-3 containment.

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[13] According to the CDC, regardless of escort, since the lab worker was not authorized to work with *Brucella*, having the lab worker help out with the aerosolization chamber during the *Brucella* experiments constituted unauthorized access to a select agent and violated the regulations.

[14] Although a person typically has to breathe in *M. tuberculosis* bacteria to get an infection, *Brucella* can enter the system through mucous membranes such as those in the eyes. During the experiment, the lab worker who got exposed had been wearing a respirator that filtered the air she breathed as is recommended for work with *M. tuberculosis*.

Developing Mechanisms for Informing Medical Providers about All the Agents that Lab Staff Work with

Severe consequences for the worker can result from delays in (1) recognizing when an exposure has occurred or (2) medical providers' accurately diagnosing any resulting infection. Further, if the worker acquires a disease that is easily spread through contact, there can also be severe consequences for the surrounding community.

In the *Brucella* incident at TAMU, at the time of the exposure on February 9, 2006, the lab worker did not know she was infected nor did anyone else in the lab. In fact, the CDC conducted a routine inspection of TAMU on February 22, 2006—13 days after the exposure—but had no way of knowing that it had happened. According to the exposed worker, it was more than 6 weeks after the exposure that she first fell ill. Then, the first consultation with her physician indicated that she had the flu; it was only after the symptoms persisted that a consultation with an infectious disease specialist confirmed that her blood contained an unknown microorganism. It was at this point that she recalled her work with *Brucella* weeks earlier. Confirmation of infection with brucellosis was made on April 16, 2006, by the Texas State Public Health Lab—62 days after the exposure. During much of this time, the worker had resumed her normal activities, interacting with many people.

In fact, the exposed lab worker had become seriously ill and the delay in recognizing her infection as brucellosis aggravated her condition. Such misdiagnosis is not uncommon with infectious diseases, as the initial symptoms often appear flu-like and brucellosis is not generally endemic in the population. If the worker had not recalled the experiment with *Brucella* and alerted her physician to this fact, according to the CDC, she might have developed an even more severe infection, possibly affecting her central nervous system or the lining of her heart.

In this incident, it was also fortunate that the disease was such that transmission beyond the initial exposed individual was difficult and that there were no risk of spread to the surrounding community. While brucellosis is not easily transferred between humans, many agents cause diseases that are easily transferred from human to human through coughing or fluid transfer, including some agents that are not select agents, such as SARS and tuberculosis.

According to BMBL, the causative incident for most laboratory-acquired infections is often unknown. It can only be concluded that an exposure took place after a worker reports illness—with symptoms suggestive of a disease caused by the relevant agent—some time later. Since clinical symptoms can take weeks to become apparent, during which time an infected person may be contagious, it is important that exposure be identified as soon as possible and proper diagnosis and prompt medical treatment provided.

Addressing Confusion over the Definition of Exposure

In addition to the incident of exposure to *Brucella*, the CDC noted several incidents of potential exposure to *Coxiella burnetii* that TAMU had failed to report. While the *Brucella* exposure eventually became apparent because of clinical symptoms in the lab worker, the *C. burnetii* incidents illustrate situations where the determination of exposure can be more problematic. In attempting to address the failure to report, questions were raised about what constitutes sufficient evidence of an exposure that the entity must report to the CDC.

One indication of exposure that can be used for *C. burnetii* and other agents is to periodically measure the titer levels—antibody levels—within the blood serum of lab workers working with those agents. If a person has a raised level over his or her baseline level, then a conclusion can be drawn that the person has been exposed to the agent. However, there are issues with using titer levels as an indication of exposure. For example, determining when the exposure took place is not straightforward.

TAMU has a program of monitoring blood serum for workers with *C. burnetii*—a select agent and the causative agent for Q fever in humans. While humans are very susceptible to Q fever, only about one-half of all people infected with *C. burnetii* show signs of clinical illness. During the CDC inspection, triggered by the uncovering of the *Brucella* incident, CDC came across clinical records that showed that several lab workers were found to have elevated titers for *C. burnetii*. But no reports had been sent to the CDC. The CDC noted this issue and, on April 24, 2007, TAMU submitted the required Form 3 to report the possible exposure.

However, as a result of subsequent discussion with the individuals who had the elevated titers, TAMU officials began to have doubts about whether or not the elevated titers resulted from exposures that had occurred at TAMU. In one case, TAMU said, one of the infected lab workers had only recently been hired by TAMU but had worked in a clinical lab in China, where *C. burnetii* was known to have been present. In another, the worker claimed to have been exposed many years earlier and had always registered high, although the actual levels varied. CDC officials disagree with this interpretation and believe the high titers resulted from exposures at TAMU.

TAMU initially responded to the uncovering of the elevated titer incidents by reporting, to the CDC, any subsequent elevated titer level uncovered in any of their lab workers. But TAMU is now unsure how to proceed. It has notified the CDC that, in its opinion, an exposure suggested by an elevated titer should be defined to have occurred only after clinical symptoms appear in the individual. TAMU has, therefore, ceased reporting incidents of merely elevated titers. In the absence of clarity over the definition of exposure, TAMU officials have chosen to define it as they see fit.

When we asked the CDC about the confusion over the definition of an exposure, officials agreed that terms need to be clearly defined and are drafting new guidance. CDC officials noted, however, that it is unwise to wait until clinical symptoms appear before determining that an exposure has taken place, as this could potentially endanger a worker's life and potentially, in the case of a communicable disease, others.

Experts have told us that correctly interpreting the meaning of elevated titers—whose characteristics can vary by agent, host, and testing lab—is challenging since many serological testing methods have not been validated. Gaps in the scientific understanding of infectious diseases—such as the meaning of elevated titers—may become more problematic as the expansion of labs continues. The development of scientifically sound and standardized methods of identifying exposure is critical, so that individual lab owners are not left to determine for themselves what is and what is not reportable.

Ensuring that BSL-4 Labs' Safety and Security Measures Are Commensurate with the Level of Risk These Labs Present

An hour-long power outage, in June 2007, at the CDC's newest BSL-4 facility raised questions about safety and security, as well as the backup power system design. The incident showed that, even in the hands of experienced owners and operators, safety and security of high-containment labs can still be compromised. The incident also raises concerns about the security of other similar labs being built around the nation.

On June 8, 2007, the CDC campus in Atlanta experienced lightning strikes in and around its new BSL-4 facility, and both primary and backup power to that facility were unavailable. The facility was left with only battery power—a condition that provides limited power for functions such as emergency lighting to aid in evacuation. Among other things, the outage shut down the negative air pressure system, one of the important components in place to keep dangerous agents from escaping the containment areas. In looking into the power outage, the CDC determined that, some time earlier, a critical grounding cable buried in the ground outside the building had been cut by construction workers digging at an adjacent site. The cutting of the grounding cable, which had gone unnoticed by CDC facility managers, compromised the electrical system of the facility that housed the BSL-4 lab.[15]

According to CDC officials, the new BSL-4 facility is still in preparation to become fully operational and no live agents were inside the facility at the time of the power outage. However, given that the cable was cut, it is apparent that the construction was not supervised to ensure the integrity of necessary safeguards that had been put in place.

Further, according to CDC officials, it was not standard procedure to monitor the integrity of the electrical grounding of the new BSL-4 facility. However, CDC has now instituted annual testing of the electrical grounding system.

Because of the power outage incident, questions about the design of the backup power system for the new facility resurfaced. When the CDC designed the backup power system for the new BSL-4 facility, it used backup generators at a central utility plant which serve other facilities, as well as functions such as chillers, on campus besides the new BSL-4 facility. According to internal documents provided to us, during design phase for the facility, some CDC engineers had questioned the remotely placed, integrated design rather than a simpler design using local backup generators near the facility.

According to CDC facility officials, the full backup power capabilities for the new BSL-4 facility are not in place yet, but are awaiting completion of other construction projects on campus. Once these projects are completed, these officials said, the new BSL-4 facility will have multiple levels of backup power, including the ability to get power from a second central utility plant on campus, if needed. But some CDC engineers that we talked to questioned the degree of complexity in the design. They are worried that an overly integrated backup might be more susceptible to failure. As a result of this power outage incident, CDC officials said, the CDC is doing a reliability assessment for the entire campus power system, which will include the backup power design for the new BSL-4 facility.

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[15] A subsequent third-party investigation determined that the grounding of another building housing CDC's older BSL-4 labs was also compromised in a similar fashion.

Some experts have suggested that BSL-4 labs be similar in design to a nuclear power plant, with a redundant backup-to-backup power system, along with adequate oversight. Like such plants, BSL-4 labs are considered targets for terrorists and people with malicious intent. Release of an agent from any of these labs could have devastating consequences. Therefore, appropriate design of labs and adequate oversight of any nearby activities—such as adjacent construction with its potential to compromise buried utilities—are essential.

Maintenance of High-Containment Labs

High-containment labs are highly sophisticated facilities, which require specialized expertise to design, construct, operate, and maintain. Because these facilities are intended to contain dangerous microorganisms, usually in liquid or aerosol form, even minor structural defects—such as cracks in the wall, leaky pipes, or improper sealing around doors—could have severe consequences. Supporting infrastructure, such as drainage and waste treatment systems, must also be secure.

In August 2007, contamination of foot-and-mouth disease was discovered at several local farms near Pirbright in the U.K., the site of several high-containment labs that work with live foot-and-mouth disease virus. Foot-and-mouth disease is one of the most highly infectious livestock diseases and can have devastating economic consequences. For example, a 2001 epidemic in the U.K. cost taxpayers over £3 billion, including some £1.4 billion paid in compensation for culled animals.[16] Therefore, the U.K. government officials worked quickly to contain and investigate this recent incident.

The investigation of the physical infrastructure at the Pirbright site found evidence of long-term damage and leakage of the drainage system servicing the site, including cracked and leaky pipes, displaced joints, debris buildup, and tree root ingress. While the definitive cause of the release has not been determined, it is suspected that contaminated waste water from Pirbright's labs leaked into the surrounding soil from the deteriorated drainage pipes and that live virus was then carried offsite by vehicles splashed with contaminated mud.

The cracked and leaky pipes found at Pirbright are indicative of poor maintenance practice at the site. The investigation found that

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[16] Department for Environment, Food, and Rural Affairs, *Foot and Mouth Disease: Applying the Lessons* (London, U.K.: National Audit Office, Feb. 2, 2005).

(1) monitoring and testing for the preventative maintenance of pipework for the drainage system was not a regular practice on site and (2) the investigation found that a contributing factor might have been a difference of opinion over responsibilities for maintenance of a key pipe within the drainage system.

High-containment labs are expensive to build and expensive to maintain. Adequate funding for each stage needs to be addressed. Typically, in large-scale construction projects, funding for initial construction comes from one source. But funding for ongoing operations and maintenance comes from somewhere else. For example, in the NIAID's recent funding of the 13 BSL-3 labs as RBLs and 2 BSL-4 labs as National Biocontainment Labs (NBL), the NIAID contributed to the initial costs for planning, design, construction, and commissioning. But the NIAID did not provide funding to support the operation of these facilities. In this case, the universities themselves are responsible for funding any maintenance costs after initial construction.

The Pirbright incident shows that beyond initial design and construction, ongoing maintenance plays a critical role in ensuring that high-containment labs operate safely and securely over time. Because even the smallest of defects can affect safety, ensuring the continuing structural integrity of high-containment labs is an essential recurring activity.

Concluding Observations

The expansion of BSL-3 and BSL-4 labs taking place in the United States is proceeding in a decentralized fashion, without specific requirements as to the number, location, activity, and ownership of such labs. While some expansion may be justified to address deficiencies in lab capacity for the development of medical countermeasures, unwarranted expansion without adequate oversight is proliferation, not expansion. Since the full extent of the expansion is not known, it is unclear how the federal government can ensure that sufficient but not superfluous capacity—that brings with it additional, unnecessary risk—is being created.

The limited federal oversight that does exist for high-containment labs is fragmented among different federal agencies, and for the most part relies on self-policing. The inherent weaknesses of an oversight system based on self-policing are highlighted by the Texas A&M University case. While CDC inspected the labs at Texas A&M in April 2006, as part of its routine inspection, its inspectors failed to identify that (1) a worker became exposed and ill; (2) unauthorized experiments were being conducted and unauthorized individuals were entering the labs; and (3) agents and infected animals were missing. It was not until a public advocacy group found out about the *Brucella* incident and, according to this group, applied pressure—by demanding records about the incident—that TAMU reported this incident to the CDC. This report prompted the subsequent in-depth investigations by the CDC.

However, this incident raises serious concerns about (1) how well the CDC polices select agent research being conducted in over 400 high-containment labs at various universities around the country, which are registered under the Select Agent Program, and (2) whether the safety of the public is compromised. Moreover, if similar safety breaches are occurring at other labs, they are not being reported. And the CDC is not finding them either. According to the experts, no one knows whether the Texas A&M incidents are the tip of the iceberg or the iceberg.

Mr. Chairman, this concludes my prepared remarks. I would be happy to respond to any questions that you or other members of the subcommittee may have at this time.

Contacts and Acknowledgments

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Appendix I: Scope and Methodology

To determine the extent of expansion in the number of high-containment facilities and the areas experiencing the growth, we interviewed agency officials and experts, as well as reviewed documents provided by agencies and the literature.

To determine which federal agency has the mission to track and determine the aggregate risks associated with the proliferation of BSL-3 and BSL-4 labs in the United States, we surveyed 12 federal agencies that are involved with BSL-3 or BSL-4 labs in some capacity—for example, research, oversight, or monitoring. The survey requested information on the agency's involvement with high-containment labs—specifically, whether the agency has a mission to track the number of high-containment labs, whether it has a need to know, and whether it knows the number of operating BSL-3 and BSL-4 labs. The agencies that received our survey include the U.S. Department of Agriculture (USDA); the Department of Commerce; the Department of Defense; the Department of Energy; the Environmental Protection Agency; the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC); the Department of Homeland Security; the Department of Interior; the Department of Justice, including the Federal Bureau of Investigation (FBI); the Department of Labor, including Occupational Safety and Health Administration (OSHA); and the Department of States. In addition, we sent our survey to intelligence agencies, including the Central Intelligence Agency (CIA), the National Counter-Terrorism Center (NCTC); the Defense Intelligence Agency (DIA); and the Office of Intelligence Analysis within DHS. We also met with officials of the Select Agent Program at both the CDC and the USDA to gain additional information about the expansion of high-containment labs. Finally, we reviewed documents these agencies provided, including pertinent legislation, regulation, and guidance, and reviewed scientific literature on risks associated with high-containment labs.

To develop lessons learned from recent incidents at three high-containment labs, we interviewed academic experts in microbiological research involving human, animal, and plant pathogens, and conducted site visits at selected federal, civilian, military, academic, and commercial BSL-3 and BSL-4 labs, including the sites involved in the recent incidents. Specifically, we conducted site visits to the CDC and Texas A&M University (TAMU); talked to the U.K. officials at Health Safety Executive and the Department for Environment, Food, and Rural Affairs; and reviewed documents and inspection reports.

To discuss the incidents at TAMU and the CDC, we conducted site visits and interviewed the relevant officials. We also conducted a site visit to the CDC and interviewed relevant officials, including the officials of CUH2A, Inc.—the contractor who designed the backup power system for the new BSL-4 lab in Atlanta—as well as the expert hired by this firm to conduct the reliability study for the backup power system.

We conducted our work from August 2006 through September 2007 in accordance with generally accepted government auditing standards

Appendix II: Pertinent Regulations

The regulations governing the Select Agent Program became effective on April 15, 1997, and were revised in March 2005. The regulations include six primary components: (1) a list of select agents that have the potential to pose a severe threat to public health and safety; (2) registration of facilities before the domestic transfer of select agents; (3) a process to document successful transfer of agents; (4) audit, quality control, and accountability mechanisms; (5) agent disposal requirements; and (6) research and clinical exemptions.

For facilities registered with the CDC and the USDA that possess, use, or transfer select agents, the select agent regulations require (1) an FBI security risk assessment for a number of individuals, including each person who is authorized to have access to select agents and toxins; (2) written biosafety and incident response plans; (3) training of individuals with access to select agents and of individuals who will work in or visit areas where select agents or toxins are handled and stored; (4) a security plan sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release, and designed according to a site-specific risk assessment that provides protection in accordance with the risk of the agent or toxin; (5) possible inspection by the CDC or USDA of the facility and its records before issuance of the certificate of registration; (6) maintenance of records relating to the activities covered by the select agent regulations; and (7) facility registration with the CDC or the USDA that indicates (a) each select agent that the entity intends to possess, use, or transfer; (b) the building where the agent will be used and stored; (c) the laboratory safety level; (d) a list of people authorized to have access to each select agent; (e) the objectives of the work for each select agent, including a description of the methodologies or laboratory procedures to be used; (f) a description of the physical security and biosafety plans; and (g) assurance of security and biosafety training for individuals who have access to areas where select agents are handled and stored.

Appendix III: The Select Agents and Toxins List

HHS Select Agents and Toxins

Abrin
Cercopithecine herpesvirus 1 (Herpes B virus)
Coccidioides posadasii
Conotoxins
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Ebola virus
Lassa fever virus
Marburg virus
Monkeypox virus
Reconstructed 1918 influenza virus[1]
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
South American Haemorrhagic Fever viruses
  Flexal
  Guanarito
  Junin
  Machupo
  Sabia
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses
  Central European Tick-borne encephalitis
  Far Eastern Tick-borne encephalitis
  Kyasanur Forest disease
  Omsk Hemorrhagic Fever
  Russian Spring and Summer encephalitis
Variola major virus (Smallpox virus) and
  Variola minor virus (Alastrim)
Yersinia pestis

USDA Select Agents and Toxins
African horse sickness virus
African swine fever virus

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[1] Reconstructed replication-competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.

Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (Exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Cowdria ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus
  (Alcelaphine herpesvirus type 1)
Menangle virus
Mycoplasma capricolum/ M.F38/M. mycoides Capri
  (contagious caprine pleuropneumonia)
Mycoplasma mycoides mycoides
  (contagious bovine pleuropneumonia)
Newcastle disease virus (velogenic)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic)

Overlap Select Agents and Toxins
Bacillus anthracis
Botulinum neurotoxins
Botulinum neurotoxin producing species of Clostridium
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly *Pseudomonas mallei)*
Burkholderia pseudomallei (formerly *Pseudomonas pseudomallei)*
Clostridium perfringens epsilon toxin
Coccidioides immitis
Coxiella burnetii
Eastern Equine Encephalitis virus
Francisella tularensis
Hendra virus
Nipah virus
Rift Valley fever virus
Shigatoxin
Staphylococcal enterotoxins

T-2 toxin
Venezuelan Equine Encephalitis virus

USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins

Candidatus Liberobacter africanus
Candidatus Liberobacter asiaticus
Peronosclerospora philippinensis
Ralstonia solanacearum race 3, biovar 2
Schlerophthora rayssiae var zeae
Synchytrium endobioticum
Xanthomonas oryzae pv. Oryzicola
Xylella fastidiosa (citrus variegated chlorosis strain)

Appendix IV: Biological Agents Recommended for BSL-3 or BSL-4 Containment that Are Not Select Agents

There are a number of biological agents causing severe illness or death that are not select agents. For example, there are five agents that are recommended for containment at BSL-4 because of (1) their close antigenic relationship with a known BSL-4 agent and (2) the fact that there is insufficient experience working with them (see table 5).

Table 5: Nonselect Agents Recommended for BSL-4 Containment

Agent	Family
Absettarov	Flavivirus
Alkhumra	Flavivirus
Hanzalova	Flavivirus
Hypr	Flavivirus
Kumlinge	Flavivirus

Source: GAO analysis of BMBL data, 5th Edition

BMBL containment and safety recommendations for *B. anthracis*, the causative agent for anthrax and a select agent, are to include the use of BSL-2 practices, containment equipment, and facilities for clinical and diagnostic quantities of infectious cultures. However, BSL-3 practices, containment equipment, and facilities are recommended for (1) work involving production quantities or high concentrations of cultures, screening environmental samples especially with powders, and (2) for activities with a high potential for aerosol production. Safety and containment recommendations for some agents, which are not regulated under the Select Agent Program, are as strict or stricter than the recommendations for *B. anthracis*. Some nonselect agents, to which containment recommendations at BSL-3 under certain conditions apply, are listed in table 6.

Table 6: Some Nonselect Agents Requiring BSL-3 Containment under Certain Conditions

Agent	Disease
Bordetella pertussis	pertussis (whooping cough)
Chlamydia psittaci	psittacosis
Mycobacterium tuberculosis complex	tuberculosis
Neisseria gonorrhoeae	gonorrhea
Neisseria meningitidis	meningitis, septicema
Salmonella typhi	typhoid fever
Hepatitis B, C, and D viruses	hepatitis B, hepatitis C
Human herpes virus	herpes simplex et al.
Noncontemporary human influenza strains (H2N2)	influenza
Lymphocytic choriomeningitis virus	aseptic meningitis, encephalitis
Lyssaviruses	rabies
Retroviruses	HIV
SARS coronavirus	SARS

Source: GAO analysis of BMBL data, 5th Edition

Appendix V: Description of Incidents at Texas A&M University

TAMU is registered with CDC's Select Agent Program and approved for work on several select agents. TAMU has several BSL-3 laboratories and works extensively on animal diseases, including those caused by the select agents *Brucella melitensis*, *Brucella abortus*, and *Brucella suis*. *Brucella* can cause brucellosis in humans, a disease causing flu-like symptoms such as fever and fatigue. But in severe cases, it can cause infections of the central nervous system. TAMU is also registered for use of *Coxiella burnetii*, an animal agent that can cause Q fever in humans.

According to the CDC, in February 2006, a lab worker was helping out with an experiment to aerosolize *Brucella*. The lab worker had no familiarity with the specifics of working with *Brucella*, but did have experience working with the aerosol chamber. It was determined that the lab worker got exposed to the agent during cleaning of the chamber after the experiment was run.

At the time of the exposure, neither the exposed worker nor anyone else had any indication that an exposure had taken place. In fact, CDC inspectors were on campus days after the *Brucella* exposure for a routine inspection but uncovered nothing that alerted them to the fact that an incident had taken place.[1] Symptoms did not start to appear in the exposed worker until more than a month after the exposure, and then the symptoms were flu-like. Confirmation of brucellosis was not made until another month had passed and symptoms had worsened. However, once the brucellosis determination had been made, the worker notified appropriate authorities at TAMU. But no report was subsequently made to the CDC as required by federal regulation and a year passed before—by chance—an independent watchdog group reviewing unrelated documentation,[2] acquired through the Freedom of Information Act (FOIA),[3] uncovered the lapse in reporting and forced TAMU to notify the CDC.

The subsequent investigation by the CDC revealed a number of other violations of the select agent regulations including (1) TAMU was not authorized to aerosolize *Brucella* in the first place; (2) a number of lab workers from another BSL-3 lab had tested positive for *Coxiella* antigens in their blood serum, suggesting potential exposures had taken place for that agent as well, but without reports going to CDC; (3) unauthorized access to select agents and toxins; (4) missing vials and animals; (5) and other protocol and procedural deficiencies.

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[1] The CDC inspected labs at TAMU on February 22, 2006, and documented 47 facility "departures," but did not note any of the violations later uncovered.

[2] The Sunshine Project, *Mandate for Failure, The State of Institutional Biosafety Committees in an Age of Biological Weapons Research* (Austin, Texas, Oct. 4, 2004).

[3] 5 U.S.C. § 552.

On April 20, 2007, the CDC issued a cease-and-desist order for all work on *Brucella* within the affected high-containment lab, as well as all aerosolization work at TAMU involving select agent and toxins. That order was subsequently expanded to include all work with select agents and toxins at TAMU—the first time the CDC has ever issued such an order entitywide under the select agent regulations. That order remains in effect as of the date of this testimony.

Mr. STUPAK. Thank you, Dr. Rhodes. Dr. Sharma, you do not have an opening statement, sir?

Mr. SHARMA. No.

Mr. STUPAK. OK. For the record, without objection, Mr. Dingell's statement will be submitted for the record.

I am sure Mr. Whitfield has one and when he comes up, it will be submitted for the record, as well as opening statements of other members of the subcommittee.

The prepared statements of Messrs. Dingell and Whitfield follow:]

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Chairman, thank you for holding this important hearing. I congratulate you for shining some much-needed light on the hidden world of bio-research, and I look forward to assisting you in this investigation as we go forward.

The central question raised by these hearings is simply this: Are these high-level biosafety laboratories safe?

The fact is that we just don't know. According to the Government Accountability Office (GAO), no single Federal agency even knows how many high-level biosafety labs there are or where they are, much less whether they are safe and secure. Moreover, no one Federal agency has the responsibility for tracking these labs and ensuring their safe operation.

Even though no one seems to know how many labs there are, the National Institutes of Health has energetically funded the construction of new high-containment biosafety labs all over the country, to the tune of more than $1 billion over the past 5 years. It is unclear whether anyone has based these funding decisions on a quantifiable assessment of need. Mr. Chairman, I intend to ask GAO to review this spending, to provide an overall accounting of how much was spent, where it was spent, and on what basis.

Although we don't know how many labs there are, GAO and other witnesses will testify that the number of high-level biosafety labs has increased dramatically over the last decade. For example, at the height of the Cold War, and as little as 10 years ago, this country had only two Level-4 laboratories—laboratories that handle deadly diseases that have no cure: one at the Centers for Disease Control and Prevention, and one belonging to the Army at Ft. Detrick, Maryland.

By next year, there will be 12 such labs in operation. Do we really need 12 laboratories that operate at the very highest level of security? Is there a good reason for creating these labs or have we simply begun an arms race against ourselves?

I had hoped that the Department of Homeland Security would be here today to assist us in answering some of these questions. I was surprised and displeased, however, to learn that even though DHS is responsible for homeland security, it declined our invitation to testify on the grounds that they were too busy and otherwise engaged.

Perhaps we need to consider compelling the attendance of the proper DHS officials at our next hearing. That would also provide DHS with an opportunity to explain their proposal to close the Plum Island Animal Disease Center off the coast of New York and move it to the mainland.

Plum Island is where the Department of Agriculture has for decades conducted research on foot-and-mouth disease. Much to their credit, they have done so safely and securely, and apparently without incident.

The DHS proposal to close Plum Island and move foot-and-mouth virus to the mainland U.S. is utterly baffling. Foot-and-mouth is one of the most contagious diseases in the world. We know from recent incidents in the U.K. that it can escape from even a high-level biosafety lab. And we know that any release of the foot-and-mouth virus could have a devastating effect on the U.S. livestock industry, just as it did in the U.K. in 2001. Why then would DHS propose to move this Level-3 biolab that works with the most dangerous animal diseases in the world from Plum Island to the heart of farm country?

I look forward to this committee's investigation of the Plum Island issue as part of this series of hearings on biosafety laboratories.

Mr. Chairman, I thank you for your recognition and look forward to the testimony of the witnesses.

Opening Statement of the Honorable Ed Whitfield
Ranking Member, Subcommittee on Oversight and Investigations

"Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States"

October 4, 2007

Thank you, Chairman Stupak. I am pleased to join you in investigating the safety and security issues surrounding the proliferation of our nation's bio-laboratories. Our examination will focus on laboratory biological research categorized at the two highest safety levels - Biosafety Level 3 and Biosafety Level 4. BSL 3 labs are used to study biological agents that are potentially deadly and transmissible, which require certain safety equipment and procedures such as special ventilation systems. BSL 4 labs handle the most dangerous agents for which there is no vaccine or treatment available, and therefore incorporate even more safety features.

The safety, security, and proliferation of bio-laboratories in our country need to be reviewed to ensure that the inherent risks associated with this type of research remain low. As members of Congress we need to be good managers and stewards of the tax-payers money while at the same time protecting the public's health and safety.

As a nation, we seek to advance public health and to confront the threat of bioterrorism. We need bio-labs to improve our bio-defense research and develop vaccines to reduce the risk of dangerous and deadly diseases and pathogens. Today we are here to begin establishing what is appropriate in terms of lab capacity, technologies, and regulations for a swift reaction in a time of need. In response to 9/11 and the anthrax attacks, Congress increased funding to upgrade our nation's bio-defense program. The National Institute of Allergy and Infectious Diseases (NIAID), which funds much of the lab research and construction, spent about $41 million on bio-defense labs in 2001 compared to spending $1.6 billion last year. NIAID has also spent about $3 billion on bio-defense research. With such a steep increase in funding and rapid expansion of the lab network, it is time to re-examine the federal regulatory system to ensure safety and efficiency.

Federal regulation of bio-laboratories is basically a hodge-podge of agencies and regulatory coverage. For example, the Centers for Disease Control (CDC) regulate labs that handle select agents posing a threat to human health. The Department of Agriculture's Animal and Plant Health Inspection Service regulates labs that handle select agents posing a threat to animal health. The National Institutes of Health is involved in the oversight of NIH-funded labs handling recombinant DNA. For some pathogens, such as hantavirus and SARS, there does not appear to be any Federal agency overseeing possession, use, and transfer. Except for select agents, there is no standard reporting system for accidents involving releases or infections.

Considerable confusion exists as to which federal agency has the mission and responsibility to monitor and oversee the increasing number of BSL 3 and 4 laboratories. The actual number of BSL-3 labs remains unknown, with reported numbers ranging anywhere from around 300 to 1,400. According to the testimony from the Government Accountability Office (GAO), no single federal agency has the mission to track the overall number of BSL-3 and BSL-4 labs in the United States.

We will also hear from the GAO and the CDC about several specific incidents involving both federal and non-federal bio-safety laboratories. More than 100 accidents and missing shipments have been reported to the CDC since 2003. We are not here today to solely criticize and focus on what happened, but rather to emphasize what we have learned from these experiences and how to prevent them from happening again.

The fragmented oversight and lack of basic general data uncovered in this investigation resembles findings from our oversight in the last Congress of human tissue samples at the National Institutes of Health. We knew that important scientific research was being done with the tissue samples, but adequate databases, controls and regulations were lacking.

This is a good opportunity to get more facts on the table and in the open. I think this is a preliminary hearing where I hope we can begin to get some answers to the questions being raised today. If the Subcommittee wishes to pursue additional hearings on this subject, we may want to consider having witnesses from the Department of Justice, the Department of Homeland Security, the Office of Inspector General at the Department of Health and Human Services, and the American Society for Microbiology, among others.

Thank you Mr. Chairman. I want to welcome and thank all of our witnesses for testifying today.

Mr. STUPAK. We will begin with questioning, 5 minutes each. I will begin. Dr. Rhodes, you mentioned select agents, how many select agents are there? These select agents being done at these labs. Is it 72?

Mr. RHODES. Seventy-two.

Mr. STUPAK. OK. One of your last statements, you indicated that there are other labs out there. You mentioned these 400 and some high-containment labs. But there are other labs out there doing other research on potentially dangerous agents and viruses and diseases, is that correct?

Mr. RHODES. Correct.

Mr. STUPAK. Do you know how many other labs that are out there that are not considered high-containment labs?

Mr. RHODES. No. That would be a larger number than the ones that are labeled high-containment.

Mr. STUPAK. Of these other labs, are they Government-sponsored labs, as in research being done at the direction or request of the Federal Government?

Mr. RHODES. Not necessarily.

Mr. STUPAK. OK. But possible?

Mr. RHODES. Possibly.

Mr. STUPAK. So agents such as SARS, dengue fever, hantavirus, they are not on these select agents?

Mr. RHODES. Correct.

Mr. STUPAK. And that research could be done in other labs that we do not know about?

Mr. RHODES. Correct.

Mr. STUPAK. And these are just as deadly as an Ebola outbreak?

Mr. RHODES. Could be, potentially, yes.

Mr. STUPAK. OK. In your testimony you said you surveyed 12 Federal agencies involved with these high-containment labs, is that correct?

Mr. RHODES. Yes.

Mr. STUPAK. And several of these agencies have a need to know within their agencies how many level 3 and how many level 4 labs are in the United States and where they are located, is that correct?

Mr. RHODES. That is correct.

Mr. STUPAK. If I read your testimony correctly of these 12 agencies, none of them, not Homeland Security, not the Center for Disease Control, not the FBI, none of the agencies actually know how many level 3 or level 4 labs are out there?

Mr. RHODES. Correct.

Mr. STUPAK. OK. The number of BSL–4 labs, those labs that handle the most dangerous and lethal diseases, have increased from two labs prior to 1990 to 15 today, is that correct?

Mr. RHODES. With one in planning. At least one is still in planning right now.

Mr. STUPAK. OK. You know, this committee also has jurisdiction, we have done investigations into our nuclear weapons research in Los Alamos and others. And it seems like in the field of nuclear we limit the number of labs doing dangerous work so we can keep the research closely regulated, under tight security, under Government control and consolidated in a few locations rather than spread across the country. With the BSL–4 labs, we could conceivably have an outbreak of something, Ebola or whatever virus spread amongst the 15 different labs with varying levels of physical security. Should not Congress want these diseases in fewer hands and fewer locations rather than more locations and more people dealing with it?

Mr. RHODES. Well, from having come out of the nuclear weapons lab program—I mean, that is my background, is in nuclear weapons side. That was the direction that we took in the establishment of the labs that are authorized to work with nuclear weapons material, particularly special nuclear material. Part of that is risk. Two laboratories were established so that there was competition between the laboratories. The idea being that you come up with a better idea through the competitive designs. But you do not expand beyond two. The more BSL–4 laboratories there are, the more opportunities for mistakes. The more opportunities there are for a release. BSL–4 handles the most dangerous biological agents. They are the ones in some cases for which there are no medical countermeasures. And so narrowing the field and bringing the number down reduces your risk because each one of these laboratories does have a baseline risk to it.

Mr. STUPAK. And one of the risks that Congress was concerned about was terrorism, right?

Mr. RHODES. Absolutely.

Mr. STUPAK. So the more labs you have out there, the more opportunity, if you will, for something to go wrong to fall into the terrorists' hands.

Mr. RHODES. The more laboratories you have, the more staff you have.

Mr. STUPAK. Correct.

Mr. RHODES. The more staff that you have to perform background investigations on. The more people who are possible to be compromised. The more material that has to be moved in order to go from point A to another lab. It becomes an extremely complex management of material problem.

Mr. STUPAK. After the anthrax problems we had in this country in the fall of 2001, Congress charged the labs to develop medical countermeasures.

Mr. RHODES. Yes.

Mr. STUPAK. Could you find anything where they said to build more labs?

Mr. RHODES. I have not found anything that said, as a result of that, build more labs. Now, the NIAID pointed out an extreme gap in the laboratory structure for countermeasure research but from the Government's direct perspective and the directives out to both industry and the scientific community and all that, it was countermeasures, not specifically build laboratories.

Mr. STUPAK. Just one more and if you know the answer, maybe you do not. There is a level 4 lab right near here in Bethesda, correct?

Mr. RHODES. That is correct.

Mr. STUPAK. Did you check that lab?

Mr. RHODES. That is one of the labs that we researched.

Mr. STUPAK. Are they doing any hot stuff there at level 4 at Bethesda?

Mr. RHODES. If I understand correctly, they are at level 3 at the moment. They are only handling level 3 agents.

Mr. STUPAK. But they are licensed or not licensed but they are a level 4 lab?

Mr. RHODES. Yes, they are a level 4 containment.

Mr. STUPAK. So it is capacity not being utilized, it is already built?

Mr. RHODES. That is correct.

Mr. STUPAK. OK. Mr. Barton for questions please.

Mr. BARTON. Thank you, Mr. Chairman. The implication in the written report is that we have too many of these level 3 and level 4 biolabs. What would a good number be?

Mr. RHODES. I do not know what a good number would be, sir. The point that we are trying to stress in the report is that no one knows what the number is. Decomposing from capacity requirement to figure out what the number is. If labs are being built just because money is available and not necessarily to meet a——

Mr. BARTON. Well, based on the need as you see it today, do we need more or less?

Mr. RHODES. I do not know whether we need more or less but we need to know the ones that we have and we need to know what they are doing.

Mr. BARTON. The report does not seem to think—I mean, I get the implication that the report indicates we have too many. I do not care if you say 10 or 100 or 2.

Mr. RHODES. The point of the report is that there is too many at the moment for the level of oversight that is being provided. So it is stretched beyond the ability of the fragmented and decentralized oversight that exists now.

Mr. BARTON. So you are not worried about——

Mr. RHODES. If the oversight is going to stay the way it is, we need less labs because the oversight that is there right now cannot keep up with the number and the expansion that is going——

Mr. BARTON. When you say the oversight right now, what do you mean by the oversight? Do we have too many agencies? Are the agencies we have not doing a good job?

Mr. RHODES. Well, we have no single agency. We have no agency that actually knows what the number is and when we go out to the agencies, we still cannot get what the number is.

Mr. BARTON. All right. How many agencies can fund one of these level 3 or level 4 laboratories?

Mr. RHODES. Well, at the moment I think it would be 15.

Mr. BARTON. So there is 15 different Federal agencies that can fund these laboratories.

Mr. RHODES. I think so.

Mr. BARTON. Is that correct?

Mr. RHODES. Yes, I think so.

Mr. BARTON. How many should there be? Should we only let one agency fund them?

Mr. RHODES. No, you can let them all fund, that is fine but who is going to provide the oversight and make certain that there is cross communication between those organizations that are funding, as well as those organizations that are providing the oversight? Right now it is a very fragmented environment.

Mr. BARTON. So you do not have a problem that 15 different Federal agencies can fund these. Your problem is or the GAO's problem, not your personal problem, but is it the agencies that fund these labs do not coordinate between each other on oversight. Is that correct?

Mr. RHODES. That is part of it and they are not coordinating on the actual need for the laboratories. So a particular department has funding and it says it has a need and it goes and funds a laboratory when, for example, let us take Texas A&M.

Mr. BARTON. Just out of pulling a name out of a hat.

Mr. RHODES. Just pulling a name out of a hat. As you said in your opening statement, they will be the model laboratory. Well, why should not they be funded by multiple agencies and make certain that there is coordination amongst the funding so that the requirements are met and why should not it be that their oversight is coordinated as well so it is not fragmented?

Mr. BARTON. I would think, to pull a name out of a hat, Texas A&M would love to have multiple sources of funding.

Mr. RHODES. I would imagine so. I would imagine many other existing laboratories would like that too. The problem is that, as the number of labs increases, the risk increases and, as that risk increases, the oversight becomes more difficult. As the oversight becomes more difficult, the transparency of what is going on in the laboratory goes away and that is the major concern. If the United States Government decides in consultation with the Congress regarding funding that there need to be 15, 20, 50 BSL–4 labs and there are needs for it and there is adequate safety and security associated with it and there is adequate coordinated oversight and it is meeting adequate requirements definition, so be it.

Mr. BARTON. If you had to pick one agency today to be the lead coordinator for this new oversight system, which agency would that be?

Mr. RHODES. I cannot say that at this moment but we will report that out in the recommendations in our final report. These are our preliminary findings but we will report that out in our final report.

Mr. BARTON. Is there an existing agency that is capable of being the lead agency for oversight that is already in existence? Can you answer me that question?

Mr. RHODES. I do not know if I can answer that question. Let me give you just one point I would make about that oversight. The oversight has to be completely independent. The oversight cannot come from someone who is operating a lab. I will give you the example from the Pirbright incident in the United Kingdom. I will be very, very surprised if anyone is ultimately held liable for the release of Foot and Mouth virus from that laboratory because the operator of the lab is the regulator. There was a private laboratory on the Government facility. Funding was coming from multiple directions. Multiple kinds of research was being done. I do not think they will be able to figure out who is ultimately responsible for the leak and who is ultimately accountable for it. And one of the complicating factors is that DEFRA, which is their version of the Department of Agriculture, is the operator of that laboratory, as well as the oversight.

Mr. BARTON. I have two more questions, Mr. Chairman. I know that my time is expired. The first question is, should these type of laboratories be allowed at academic institutions generically?

Mr. RHODES. Yes, I do not see why not. I mean, that is the——

Mr. BARTON. So it is not a problem per se that it is at an academic institution?

Mr. RHODES. It is absolutely not an issue of where the laboratory is located. Obviously, people are going to have to have open hearings about where it should be. It is not a question of academia.

Mr. BARTON. Last question, Mr. Chairman. The laboratory at Texas A&M, was it level 3 or level 4, do you know?

Mr. RHODES. It is a level 3.

Mr. BARTON. Thank you. Thank you, Mr. Chairman.

Mr. STUPAK. Just a question. I mentioned about Bethesda being 3 and Mr. Barton mentioned about level 3. If a lab goes from 3 to 4, is the community around it aware or told what the agent or that is known?

Mr. RHODES. It may not be.

Mr. STUPAK. There is no requirement either way?

Mr. RHODES. I have not seen any documentation so far that there has to be a public hearing about a laboratory being allowed to go from 3 to 4. There may be a requirement for a public notice but I have not seen documentation that says that so far.

Mr. STUPAK. I mentioned in my opening that we intend to also examine level 3 and 4 labs internationally and we intend to examine the proposal to close Plum Island and relocate the foot-and-mouth disease research to the mainland. Will GAO continue to work with the committee on that investigation research?

Mr. RHODES. Yes.

Mr. STUPAK. OK, thank you. Ms. DeGette for questions please.

Ms. DEGETTE. Thank you very much, Mr. Chairman, and I appreciate you holding these hearings which are continuations of hearings this committee has done for a number of years. I was telling staff about several years ago when I went to the level 3 lab, the CDC lab, up in Fort Collins, Colorado. And the lab at that time, they had vector-borne agents there and these vector-borne agents were being stored in a modular unit behind the building that had weeds growing up from the floor and it had flies flying—these are vector-borne agents and I am happy to report that since I visited that and with the assistance of my former colleague, Bob Shaffer, we succeeded in having a new CDC lab built there. I assume they have eliminated the weeds and the flies. But I was really dismayed about your testimony that we now have a proliferation of these level 3 and 4 labs since 2001. Doctor, I am wondering if you can tell us why you think that we have had such a proliferation of these labs?

Mr. RHODES. There is a perceived gap, and actually stated by NIAID, that there is a need post-fall of 2001 events with the anthrax through the mail, for a response network to a future terrorist event. Also a perceived need for ability to do research on countermeasures. And as a result of that, as I stated, both the administration and the Congress have given funding to meet this requirement.

Ms. DEGETTE. And that is going to a wide range of types of private and public entities?

Mr. RHODES. Yes, ma'am.

Ms. DEGETTE. So there has been no distinction made. I think you pointed this out. There has been no distinction made between governmental oversight and private or academic labs, correct?

Mr. RHODES. That is correct.

Ms. DEGETTE. And is it your view—I know you told Mr. Barton that you did not have an opinion yet on which agency should be the lead agency in overseeing these labs but my question is, do we even want more than one agency overseeing level 3 and 4 labs right now? We have got the CDC, the USDA, the DOD and others. Do we want a coordinating lab or do we want just one single agency with authority over regulation of all of these labs?

Mr. RHODES. That would ultimately be the simplest answer.

Ms. DEGETTE. One agency coordinating.

Mr. RHODES. One agency. But that said, the agency that does the oversight will ultimately end up being a coordinating agency because they will have to go to each of the departments and agencies that are funding and go to any of the laboratories and will have to coordinate with them relative to requirements and all that.

Ms. DEGETTE. But the advantage would be you would have one set of standards that would be implemented, correct?

Mr. RHODES. That is correct.

Ms. DEGETTE. Dr. Sharma is nodding in agreement. And so when do you think you will have your recommendation as to what that agency and process should be?

Mr. RHODES. Our schedule right now is to issue our final report in February.

Ms. DEGETTE. February 2008?

Mr. RHODES. Yes, 2008.

Ms. DEGETTE. Thank you.

Mr. RHODES. And we will have to put it out for comments, so I would say probably by March.

Ms. DEGETTE. OK. Now, as I mentioned, not all of these level 3 and 4 labs are federally supported. Some of them are State supported or even private. I am wondering if these non-federally funded labs have unique concerns about which we should be aware and which we should think about as we think about further regulation.

Mr. RHODES. A non-federally funded laboratory is, in effect, an information black hole, so you do not have any insight into it. Unless they are part of the select agent program or they are federally funded, the United States Government will not have any insight into who owns it, where it is, what they are doing.

Ms. DEGETTE. What their protocols are.

Mr. RHODES. Absolutely.

Ms. DEGETTE. And what can Congress do to address that issue?

Mr. RHODES. That would be part of the charter, I guess of the new oversight. They would have to have powers of authority to talk to and gain information from all BSL–3 and 4 laboratories, not just the ones that the Government has oversight of because it is a public safety issue.

Ms. DEGETTE. What you are saying, I think based on your experience with the nuclear labs, what we would have to say is, if a lab had in its possession a certain type of these agents, they would automatically be regulated federally and it is not happening now.

Mr. RHODES. Well, let us look at nuclear power for example. You have the Nuclear Regulatory Commission. Well, the Nuclear Regulatory Commission is not just talking about commercial power.

Ms. DEGETTE. Right.

Mr. RHODES. Talking about anyone who is handling a radio nuclide.

Ms. DEGETTE. Right.

Mr. RHODES. So if your transportation person who is using cesium gauges in order to figure out the depth of a freeway.

Ms. DEGETTE. Right. But what——

Mr. RHODES. You are licensed.

Ms. DEGETTE. And what I am saying is, right now we do not have that same authority over these biologic agents.

Mr. RHODES. Absolutely.

Ms. DEGETTE. If someone can just set up one of these labs and if it is privately funded then, what you are saying is, we are not regulating that.

Mr. RHODES. Correct.

Ms. DEGETTE. Yes, Dr. Sharma wants to add——

Mr. SHARMA. I would add, this is a very essential issue because these BSL–3 and 4 labs in the United States do not need any kind of permit other than building permits if they are not receiving any Federal funds. There is no certification requirements. They can operate. In addition to that, we have additional problems. There are these mobile labs. You can build it. So it is a very complex issue and right now, our system is, there is no way for any agency to know but we are looking at some other systems in other countries. There are requirements to see the extent of which those systems could be applied here and we will be reporting those as part of our report in February.

Ms. DEGETTE. And as I said, what those systems would be is similar to the system that we use for nuclear material, which is if you are in possession of these agents and you are going to have a lab, then you have to meet certain requirements, correct?

Mr. RHODES. Yes.

Ms. DEGETTE. And is that part of what you are developing for next spring?

Mr. RHODES. That is the direction we are looking.

Ms. DEGETTE. I think the committee would all agree that is an extremely important set of guidelines. And I want to thank you both for coming today.

Mr. RHODES. Thank you.

Ms. DEGETTE. I yield back.

Mr. STUPAK. Mr. Burgess for questions, please.

Mr. BURGESS. Thank you. Dr. Sharma, if I could just pick up on what you were just saying as you concluded your response to Ms. DeGette. So if there is no Federal funding involved, the only permitting is local building permits?

Mr. SHARMA. Right.

Mr. BURGESS. Did I understand that correctly? So then there is no one that certifies whether this is a level 3 or a level 4 facility?

Mr. SHARMA. It is our understanding that if you are not receiving any Federal funds, if you are not working the select agents, there is nobody you have to seek permission from other than city or State requirements.

Mr. BURGESS. So to answer the chairman's question about who in the surrounding community is notified, then, obviously, no one would be notified in that situation, is that correct?

Mr. SHARMA. Correct.

Mr. BURGESS. Have you looked at all, and obviously other—we have heard a little bit about the foot-and-mouth disease incident in Great Britain. What are the systems in other countries? How are they dealing with this? Because clearly this is something that is a process in evolution, it is a concept that is developing. Where are other countries on that continuum of development of their regulation of these types of labs?

Mr. SHARMA. We have not extensively looked at other foreign systems and we have plans to look at how other countries are handling this issue.

Mr. STUPAK. And we have asked them to do that, Mr. Burgess, look at other areas internationally. Not only for safety but you see countries like Sudan and China suddenly coming up with level 4 labs. I wasn't quite concerned to go to China yet but I was working there.

Mr. BURGESS. OK.

Mr. STUPAK. Dr. Rhodes, you had something you wanted to say?

Mr. RHODES. Let me just make one point. I was in the UK and was talking to the people at the Pirbright site. There is currently the exact same discussion that your colleague from Colorado was discussing. They are trying to figure out who is going to be the single regulator because they have the split, they only have two but one is for animals and one is for human pathogens. And then there is that area in-between, which is called zoonotics. Those are the agents that affect both animals and humans. So what is probably going to come out from that discussion is there will be a single regulator. There will be a single set of regulations. Obviously, they have to be tailored for working with animals versus humans. There will be no allowance for the regulator to be an operator. But that is the discussion that is going on right now in the UK as a result of the Pirbright outbreak.

Mr. BURGESS. Let me ask you the question, as it pertains to the single agency regulations with radio nuclides, zoonotics are a little bit different because here we have got a select list or select agents which is somewhat arbitrary, I would argue. I am by no means an expert but, I mean, SARS not being on that list is, well, a striking omission and I am sure there are good reasons why, from a research perspective, that someone has come up with that designation. But it just points to the difficulty when we talk about we want to do things to remove ambiguity. But there are inherent ambiguities in this system. Heisenberg's Uncertainty Principle probably applies here more so than the field of radiation sites, is that not correct?

Mr. RHODES. I follow your logic on that.

Mr. BURGESS. I do not think it was logic but I appreciate your calling it that. Let me ask you this. I mean, obviously, we got to this system because someone said there is a threat and there is value to developing a rapid response. Do I understand that correctly?

Mr. RHODES. That is correct.

Mr. BURGESS. I wasn't here in 2001. And then when I was here in 2003, we had the SARS kind of just crop up all at once and it was handled correctly. It was handled correctly from a lot of different levels at the CDC and the NIH and identifying it as a coronavirus, identifying where it came from. And really with no vaccine and no specific treatment, we were able to beat back the threat of an epidemic very, very quickly with old fashioned tools, epidemiology and quarantine. So, clearly there is value here in developing this expertise. I guess my only point is I hope there is some caution, in bringing down the regulatory hammer here, that we not cripple a system that delivered us from evil in the case of SARS relatively quickly, very competently and although 800 people did die, it could have been just extravagantly worse had we not been at the top of our game on that particular illness.

Mr. RHODES. And that is a very good point. I want no one to take our preliminary findings and think we are trying to throw the baby out with the bathwater. In answer to Representative Barton's question about academic environment, I came out of an academic environment. Dr. Sharma came out of an academic environment. We have all come out of academic environments. And with our scientific backgrounds, we couldn't have them without academic environments. So it is not saying be Draconian about this. It is saying let us not be Byzantine about it. The fabric of oversight now is so convoluted I would defy anyone—I mean, I have a very, very smart team and we cannot figure it out. And we talked to people who have regulatory authority and, as a matter of fact, one of them said "that would be nice if we could know that, anything you can do to help us would be appreciated." Now, if somebody goes to the GAO and asks for help, they are in a hot spot.

Mr. BURGESS. Well, your table that you provided, page 12, and in your evidence book, tab 23, just comparing those two maps of the United States where the locations of the labs are strikingly different. So I think the ambiguity there speaks for itself that we do not even know where we are, what we got and what we are doing and clearly that is the thrust of this committee. Mr. Chairman, I thank you for your indulgence. I will yield back.

Mr. STUPAK. I thank the gentlemen. Dr. Rhodes, in your survey, did any of the Federal agencies that you looked at, did they indicate concern about the proliferation of these high-containment labs?

Mr. RHODES. Oddly enough, the Federal Bureau of Investigation and the Intelligence Community were the ones who were most concerned about it. Obviously, they have the counterterrorism side and they have the national security side and they have the national intelligence estimate side. But the FBI also had another concern, which was they are the ones who have to clear the staff. So on one side they have the operational mission of trying to keep people safe and on the other side, they have the operational issue of trying to figure out if the people are actually trustworthy. And as the number of laboratories balloons their workload balloons, their ability to collect intelligence diminishes. And that was their largest concern.

Mr. SHARMA. I would also like to add here that if there is another accident, it is their responsibility to find out where the material came from. And if they do not know how many labs there are or where the potentials are, they cannot find the perpetrator. And in particular, I think they are in the process of resolving this issue, the CDC, we have been told. But up until now, they could not even obtain the listing of select agent labs that are registered with CDC and this makes their job very difficult. In addition, the main intelligence agency in general have concerns about this proliferation of labs especially not having a centralized Federal vision of what our needs are and how those needs are going to be met. Right now it is fragmented and they are concerned about it.

Mr. STUPAK. OK. Mr. Green for questions.

Mr. GREEN. Thank you, Mr. Chairman. And Dr. Rhodes, I have a series of questions but I think the table on page 13 shows a shocking amount, that no Federal agency has the mission to track high-containment labs in the United States and you go down a number of departments and none of them have that ability. I am interested in the select agent program. It appears that the use of select agents triggers a lab's responsibility to register with the CDC. Would you agree?

Mr. RHODES. Yes.

Mr. SHARMA. Yes, sir.

Mr. RHODES. And USDA.

Mr. GREEN. And USDA. I noticed that agents such as SARS are not currently on the list. It trumps me to wonder when the list was last updated. I know that Congress updated the list in 2002 with the bioterrorism bill. Was that the last time there was any statutory change?

Mr. RHODES. To the best of my recollection, that is the last time there was a statutory requirement.

Mr. GREEN. OK. I know that the CDC and USDA have jurisdiction over the regulation and oversight of the actual labs. What about the agents being studied in the labs, does any regulatory agency have the authority to update the list of these select agents?

Mr. RHODES. We do not know that answer.

Mr. GREEN. You do not know if there is any agency who can update that list of the select agents? That is basically the question.

Mr. RHODES. The CDC.

Mr. GREEN. The CDC?

Mr. RHODES. Yes.

Mr. GREEN. What agency, in your views, is best poised, is it CDC? Do you know when they last updated that list?

Mr. RHODES. The last update, as I understand it, was in response to the 2003 requirement.

Mr. GREEN. On other agents other than, for example, SARS, what agents do not appear on this select agent list? Is there any Federal regulation or inventory of the use of any of these agents?

Mr. SHARMA. There is a process in place. As you know, there are emerging threats constantly. There is a mechanism whereby the list can be updated but we have not specifically looked at the process itself, how long it takes and what is involved in updating the list.

Mr. GREEN. OK. The CDC inspected the Texas A&M lab in February 2006 and it was a full 13 days after an employee was exposed to *Brucella* and was incapable of discovering the exposures. Is this an inherent deficiency in the inspection process or is this specifically an omission by the CDC in this instance?

Mr. RHODES. I think it is one of the problems in the ability of CDC to inspect. Let me give you a counterpart from the UK. The HSE, which is the Health Safety Executive, has inspectors. The inspectors are warranted. They have law enforcement authority. They can compel testimony. They can dig up a pipe if they want to. They can kick in a wall if they have cause to. They can show up with constables if they need to, if they think that they are in danger of personal harm because the Health Safety Executive looks into all kinds of public safety issues, not just biolabs. But the U.S. Government does not have a counterpart to that.

Mr. SHARMA. Let me add a few things here. I think CDC's system of inspection relies on documentation and people honestly reporting the facts. And if they are not going to, they are not going to find out. It is very simple. The second thing is, and we have shared this and there are other systems in place like in this case, NIH has guidelines on rDNA under which they require institutions that receives Federal funding to have institutional biosafety committees and they also must document the minutes of those meetings. So it is coming from another part of the Government which CDC, it is our understanding and in the process very labor-intensive, I must say this, to review all those minutes. It was documented that this person was exposed to. Now, if it wasn't for the fact that the Sunshine Project Group took the pain to obtain and review and identify this incident, there was no way. It is really the responsibility of the institutions to report to CDC. And if they are not going to, there is not much that can be done and not much we can find out.

Mr. GREEN. OK. Mr. Chairman, I know I am out of time. I have another question that I would like to submit basically on what the GAO found was a primary source of the incidence of the biosafety labs and would you attribute it to majority of accidents to human error or engineering or design flaws of the system and I will submit that in writing, Mr. Chairman.

Mr. STUPAK. OK, very good.

Mr. RHODES. Thank you.

Mr. STUPAK. Mr. Inslee, questions please. We have six votes on the floor, let us get this panel in if we can and then we will take a break.

Mr. INSLEE. Thank you. Is there evidence that the anthrax attack on the Senate was essentially a way to provoke this inquiry we are having in this hearing? Was that the effort? Is there any evidence to suggest that or not?

Mr. RHODES. We have seen no evidence to support that hypothesis.

Mr. INSLEE. Well, I guess it would not make a difference. We have an issue and we have to deal with it, I suppose in any event. I've been told that there was a proposed study by NIH about the risks associated with proliferation of labs and the like that was to be completed. We have not seen it yet. Have you seen an NIH assessment of this issue?

Mr. RHODES. No, we have not seen that.

Mr. INSLEE. Is there anything forthcoming from them that you are aware of or not?

Mr. RHODES. We do not know of anything, sir.

Mr. INSLEE. OK. If we do develop some more uniform protocol for oversight of these labs, I assume there will be some concern about the military aspect of this. It is always difficult when you try to blend oversight of civilian and military operations and the military has concerns about that for understandable reasons.

Mr. RHODES. Yes.

Mr. INSLEE. How would we go about having a consistent oversight when we have a military operation that, I would assume, be part of that?

Mr. RHODES. Well, that is one of the models we are looking at in the UK because both DEFRA, as well as the Health Safety Executive, have oversight of both civilian and military. They have the Ministry of Defense laboratories under their oversight, so we will look into that and be able to report about.

Mr. SHARMA. CDC also, if the military labs are working the select agents, they also have to be registered with CDC and CDC does provide the same oversight as they provide to other civilian institutions.

Mr. INSLEE. OK. You mentioned that some of these existing requirements apply only if the facility is receiving Federal money. Is it likely to have more of this work done in areas where there is not Federal money? We have the situation with stem cells right. We have a proliferation of labs, some not taking Federal money just so they can continue the stem cell research because of the ridiculous restrictions we have on Federal funding. Are we going to see more strictly privately-funded labs here? If we do have requirements, should it apply to everyone not just those who are receiving Federal money?

Mr. RHODES. We may. One of the problems in trying to answer your question is that I have to have some baseline of data. And because privately-funded labs, if they are not using select agents or are not federally funded, we do not know about them; then I cannot even speculate on where that would go.

Mr. INSLEE. Do you think we need some regulatory process for all labs, federally or non-federally funded, whether or not they use these specific agents? Are there risks associated with certain activities that we are not picking up in our system?

Mr. RHODES. Yes, there are. There are agents that are not on the select agent list and they have grave consequences as well. And whether regulation is direct regulation or not or whether it is just that we need to know where they are. I mean, right now, we do not even know where they are and we do not know what is being done and we do not know who is doing it. And from my standpoint and my colleague's, as well as a lot of safety professionals and security professionals, including our own Federal Bureau of Investigation and our own Intelligence Community, that is a worrisome subject.

Mr. INSLEE. You are not alone. We should do something. Thank you.

Mr. RHODES. Thank you.

Mr. STUPAK. Thank you, Mr. Inslee. Mr. Inslee asked the question: did you find any study to assess the need for more of these level 3 and level 4 labs and you said you did not come across any study?

Mr. RHODES. We have not come across any.

Mr. STUPAK. Did you request from NIH, CDC or U.S. Department of Agriculture any kind of justification of proliferation of these labs? Dr. Sharma?

Mr. SHARMA. NIAID in collaboration with the American Society of Microbiology did conduct this survey trying to ascertain what our lab capacity is. But this study had some methodological problems. Primarily one major being very low response rates. And we do have that study. But in addition to that, we do not have anything else.

Mr. STUPAK. So they tried to do a study but it was such a low response, you couldn't make a determination from that assessment?

Mr. SHARMA. Right.

Mr. STUPAK. So we still do not know what is the right capacity or number of labs that we need?

Mr. SHARMA. Well, if you do not know the universe of labs and their capabilities, you cannot obviously meet any——

Mr. STUPAK. Correct. If you do not know its abilities or what they are doing you cannot make the assessment.

Mr. SHARMA. Right.

Mr. STUPAK. Mr. Burgess, anything before I let this panel go?

Mr. BURGESS. I think Mr. Barton referenced in his opening statement, talking about the anthrax attack and when there was a Senate hearing there was a question posed to the FBI back in 2001, the FBI was asked how many labs handle anthrax of this type and I guess no one knew the answer to that question.

Mr. RHODES. That is correct.

Mr. BURGESS. Do we know the answer today?

Mr. RHODES. No.

Mr. BURGESS. Well, let me ask you this. Obviously, we have put some time and effort into protecting the homeland with the proliferation of labs, is it the opinion of the two individuals before us from the GAO that we have moved on that continuum of being more secure or are we stationary or are we less secure?

Mr. RHODES. That fact that there is so much that is unknown at the moment, I would have to say we are at greater risk. Because as the number increases, the risk increases and it is not just the increase in the material, it is the increase in laboratories that have less experience than others.

Mr. BURGESS. So the actual risk may be generated by the fact that we are studying to prepare for the risk?

Mr. RHODES. Yes. It is a dilemma that we are in.

Mr. BURGESS. But that is one of the prices you pay for doing the research, correct?

Mr. SHARMA. That is correct.

Mr. BURGESS. And you'll never get to a point of relative security if you are not willing to invest the time and effort and the risk in doing the research, is that correct?

Mr. RHODES. That is correct but doing——

Mr. BURGESS. And we need to manage the risk.

Mr. RHODES. Yes. We are not——

Mr. BURGESS. So my question is, are we doing a good job of managing the risk. I would assume the answer to that question today is no.

Mr. RHODES. No.

Mr. BURGESS. But is it your opinion that we can get to that point of managed risk which now is acceptable?

Mr. RHODES. Yes, we can. It could be done.

Mr. BURGESS. Thank you. I yield back.

Mr. STUPAK. OK. Just along those lines though, today we are only talking about buildings. We have not talked about the quantity, quality, string of agents that are out there and who is doing what at what labs and things like that. We do not even know that.

Mr. RHODES. That is correct.

Mr. STUPAK. OK. Future hearing. We have six votes on the floor. Let us look for about 12:00, 12:15 we will be back. We will dismiss this panel. Thank you very much and thank you for your work and we will continue this investigation. So we will stand in recess for 45 minutes, 50 minutes.

[Recess.]

Mr. STUPAK. It is one of those days, as I said, there is a hearing going on on the third floor and we have got about three hearings going in the Energy and Commerce Committee. So we have our second panel of witnesses and they are Dr. Richard Besser, who is the Director of the Center for Disease Control and Prevention, Coordinating Office of Terrorism Preparedness and Emergency Response. Dr. Casey Chosewood, who is director of CDC's Office of Health and Safety; Captain Robbin Weyant, who is the CDC's Director of Division of Select Agents and Toxins; and Dr. Hugh Auchincloss, who is the National Institutes of Health, Deputy Director of National Institute of Allergy and Infectious Diseases. It is the policy of this subcommittee to take all testimony under oath. Please be advised witnesses have the right under the rules of the House to be advised by counsel during your testimony. Do any of you wish to be represented by counsel? No one is indicating no, so therefore I will ask you to please rise, raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses have answered in the affirmative. You are now under oath. It is my understanding Dr. Besser and Dr. Auchincloss are going to be the only ones giving testimony, is that correct? Dr. Besser, you want to start with you please, sir?

STATEMENT OF RICHARD BESSER, M.D., DIRECTOR, COORDINATING OFFICE FOR TERRORISM, PREPAREDNESS AND EMERGENCY RESPONSE, CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. BESSER. Thank you. Good afternoon, Chairman Stupak, Ranking Member Whitfield, the members of the subcommittee. I am Dr. Richard Besser, Director of the Coordinating Office for Terrorism Preparedness and Emergency Response at the Centers for Disease Control and Prevention.

Accompanying me today are Dr. Rob Weyant, who is the director of our Division of Select Agents and Toxins and Dr. Casey Chosewood, who is director of CDC's Office of Health and Safety. On behalf of CDC, I am pleased to be here today to discuss how CDC oversees select agents in the Nation's laboratories.

To further scientific knowledge about biological agents and toxins and develop diagnostic tests and countermeasures against them, our institutions conduct research on these potentially harmful agents. Before undertaking any laboratory experiment, it is critical that one weighs the potential benefits of the experiment against the potential risks. We recognize that such research increases the risks of accidental or intentional release of these agents. To mitigate this risk, Congress authorized the Federal Government to oversee labs that work with select agents. The creation of this program has given our Nation an important tool to help minimize the inherent risks that accompany work with select agents. The regulation of select agents is a shared Federal responsibility between the Department of Health and Human Services, Agriculture and Justice. Congress gave HHS the authority to regulate the possession, use and transfer of biological agents and toxins that could pose a severe threat to public health and safety. We refer to these as select agents. No program for oversight of select agents existed in the United States prior to 1996. In 2002, Congress significantly strengthened oversight of select agents with the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The select agent regulations that were established as a result of this Act are the ones that are currently in effect.

It is important to note that not all laboratories work with select agents. Therefore, not all laboratories are regulated under the provisions of the select agent regulations. For instance, HIV and the bacteria that causes tuberculosis are not select agents and are not covered by the program. However, the Federal Government does provide biological safety guidance to the entire laboratory community through a document entitled, "Biosafety, Microbiological and Biomedical Laboratories."

Laboratories have multiple systems in place to ensure biosafety. The first line of defense is proper training of lab workers. Before someone can work in a lab, they should undergo rigorous lab safety training. People who work in labs also are physically protected through the use of personal protective equipment such as gloves, masks, goggles and for the most dangerous germs, biosuits. Laboratories also are engineered to ensure that dangerous pathogens cannot escape. Some of these engineering controls include negative air pressurization and the use of biosafety cabinets. Accidents can and will happen in labs. But these multiple biosafety systems can help to ensure that lab workers and the public are protected.

CDC executes the select agent program through both a strong oversight role by evaluating and inspecting registered labs and by providing guidance and training to those labs. Routine inspections are conducted a minimum of every 3 years. Additional inspections are conducted any time that an entity requests a significant change to its select agent registration. An important tenant of the CDC's select agent program is that it treats all registered labs the same, whether that lab is a commercial lab, State or local public health lab or Federal lab, including CDC and Department of Defense labs.

The select agent program uses standardized checklists to inspect all labs, has the same requirements for all labs and uses the same standards when referring any lab to the HHS Office of Inspector General for possible violations of the regulations.

Public concerns and questions about the overall safety of our Nation's laboratory workers are understandable and legitimate. In the 4 years that the select agent program has been in place with approximately 400 organizations being registered and after careful investigations when a potential incident has been reported, there have been no confirmed losses or thefts of a select agent and there have been three confirmed releases of a select agent. After careful investigation, none of these releases were considered to be a public health threat.

This does not mean, however, that such incidents cannot happen in the future. Even a lab that follows all biosafety guidelines may have accidents. But the biosafety and biosecurity requirements that Congress established help reduce the likelihood that these accidents will impact worker or community health.

We have accomplished much since the program began but we are always looking for ways to improve. Investigations of labs have taught us important lessons. We have learned that we need to make improvements during inspection verification processes. In the future during our inspections, we plan to expand the scope of interviews and review a broader array of documents to identify problems that may go unreported by registered labs. In addition, we plan to assess the composition of our inspection teams and the frequency of our inspections. We also have learned that we need to provide additional outreach and training to the regulated community and create additional guidance documents. We will be undertaking an external review of the CDC's select agent program so that we can continue to improve our oversight of select agent work. The external group conducting this review will actively solicit the input of stakeholders and the general public. In addition to this review, the HHS Office of Inspector General is conducting an audit of CDC's management of its select agent program. We look forward to the findings and recommendations scheduled for completion in 2008 and using this work to help strengthen our program.

In conclusion, the select agent programs at CDC and USDA, working in concert with the Department of Justice, have greatly enhanced the Nation's oversight of dangerous biological agents and toxins. The select agent regulations have helped ensure that research with select agents is conducted as safely and securely as possible. However, the possibility of accidental or intentional release of these agents always remains so we must remain vigilant and work to continuously improve our oversight. We will continue to enforce the regulations and provide technical assistance and guidance to the regulated community to ensure that the public's health and safety are protected.

CDC greatly appreciates the support of this subcommittee and the rest of Congress in supporting its activities. We look forward to continuing our work with you on these important issues. Thank you for the opportunity to share this information with you and I look forward to answering questions.

[The prepared statement of Dr. Besser follows:]

STATEMENT OF RICHARD E. BESSER, M.D.

Good morning Chairman Stupak, Ranking Member Whitfield and members of the Subcommittee. I am Dr. Richard Besser, Director of the Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER) at the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services. Accompanying me today are Dr. Rob Weyant, Director of the Division of Select Agents and Toxins in COTPER, and Dr. Casey Chosewood, Director of the CDC Office of Health and Safety. On behalf of CDC, I am pleased to be here today to discuss how CDC oversees select agents in the Nation's laboratories.

To further scientific knowledge about biological agents and toxins and develop countermeasures against them, our academic, commercial, and government institutions conduct research on these potentially harmful agents. We recognize that such research increases the risks of accidental or intentional release of these agents. To mitigate this risk, Congress authorized the Federal Government to oversee labs that work with select agents—which include such things as Bacillus anthracis (which causes anthrax), Yersinia pestis (which causes plague), and Variola major virus (which causes smallpox). The creation of this program has given our nation an important tool to help minimize the inherent risks that accompany work with select agents.

The regulation of select agents is a shared Federal responsibility involving HHS, the Department of Agriculture (USDA), and the Department of Justice (DOJ). Congress gave HHS the authority to regulate the possession, use, and transfer of biological agents and toxins (select agents) that could pose a severe threat to public health and safety. The Secretary of HHS has delegated this authority to CDC. Congress gave USDA similar authority to regulate select agents that pose a severe threat to animal and plant health and/or animal and plant products. DOJ is responsible for conducting background checks, called security risk assessments, of any entities and individuals that want to work with select agents. By regulating the possession, use, and transfer of select agents, HHS, USDA, and DOJ contribute to the Nation's overall terrorism deterrence strategy.

My testimony will focus on CDC's role in the regulation of select agents. I will describe the history of the CDC Select Agent Program, CDC's role in oversight of select agent laboratories, our collaboration with other Federal partners, the key components of the CDC regulatory program, key program accomplishments, and our future plans for enhancing the program.

Establishing Oversight over Select Agents: A Brief HistoryNo program for oversight of select agents existed in the United States prior to 1996. In 1996, Congress passed the Antiterrorism and Effective Death Penalty Act of 1996 (P.L. 104–132; signed April 24, 1996). With the regulations that went into effect in April 1997 (42 CFR 72.6), the Secretary of HHS established a list of biological agents that have the potential to pose a severe threat to public health and safety. The Secretary also established procedures for the transfer of these biological agents. The CDC Select Agent Program has been in place since 1996. The program was originally located within CDC's Office of Health and Safety and is now located within CDC/COTPER's Division of Select Agents and Toxins.

In 2001, Congress expanded the scope of the program by restricting the shipping, possession, and receipt of select agents by passing the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act); (P.L. 107–56; signed Oct. 26, 2001). The USA PATRIOT Act created a provision related to select agents requiring that no restricted person shall transfer (i.e., ship, possess, or receive) a select agent.

In 2002, Congress significantly strengthened oversight of select agents with the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act); (P.L. 107–188; signed June 12, 2002). The Bioterrorism Act strengthened the regulatory authorities of HHS under Sec. 511 of the Antiterrorism and Effective Death Penalty Act of 1996 and granted comparable regulatory authorities to USDA for select agents that present a severe threat to animal or plant health, and/or animal or plant products. It also required coordination and concurrence between HHS and USDA on program activities (e.g., development of regulations, reporting forms, approval of changes to regulated laboratories—registrations, et cetera) for select agents regulated by both agencies.

The Bioterrorism Act has been implemented through a series of regulations. HHS published an interim final rule—the "Possession, Use, and Transfer of Select Agents and Toxins" Interim Final Rule (42 CFR 73, 9 CFR 121, and 7 CFR 331) (effective on February 7, 2003) which implemented the pertinent provisions of the Bioterrorism Act. A subsequent Final Rule became effective on April 18, 2005. On October 20, 2005, HHS established an Interim Final Rule adding reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments to the HHS select agent list. These regulations are hereafter referred to as the "select agent regulations".

ROLE OF THE SELECT AGENT PROGRAM IN OVERSIGHT OF LABORATORIESNOT ALL LABORATORIES HANDLE SELECT AGENTS

Whereas HHS and USDA have authority to regulate any laboratories that possess, use, or transfer select agents, not all laboratories work with select agents. Therefore, not all laboratories are regulated under the provisions of the select agent regulations. For instance, human immunodeficiency virus (HIV) and Mycobacterium tuberculosis are not select agents and any laboratories working with these agents are not required to register with either HHS or USDA.

All five currently operational Biosafety Level (BSL) 4 laboratories in the United States are select agent registered entities. (Any organization that has received a certificate of registration through either the HHS or USDA Select Agent Program is referred to as a ″registered entity″.)

FEDERAL GOVERNMENT GUIDANCE TO BIOLOGICAL LABORATORIES AND RELATED REQUIREMENTS

Though only a subset of laboratories is regulated by the Federal Government under the provisions of the select agent regulations, the Federal Government does provide biological safety guidance to the entire laboratory community. The Biosafety in Microbiological and Biomedical Laboratories (BMBL) (4th edition is available in print; 5th edition is available at *http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm),* produced by CDC and the National Institutes of Health (NIH), is a nationally and internationally recognized source that provides safety guidance to laboratories that work with infectious agents. The BMBL provides recommendations for safely working with a variety of human pathogens and describes standard and special microbiological practices, safety equipment, and facilities (constituting Biosafety Levels 1–4). In the BMBL, there are agent summary statements that provide recommendations for the appropriate biosafety safety level to work with these agents. The BMBL also is offered as a guide and reference in the construction of new laboratory facilities and in the renovation of existing facilities.

CDC references the BMBL in the select agent regulations and requires select agent registered entities to comply with the BMBL guidelines or equivalent standards. Specifically, the select agent regulations state that the entity should consider the BMBL, NIH's Recombinant DNA Guidelines, and the Occupational Safety and Health Administration's regulations on handling toxins (29 CFR 1910.1200, 29 CFR 1910.1450) in developing and implementing a written biosafety plan that is commensurate with the risk of the select agent, given its intended use. If the Select Agent Program determines that the entity's biosafety and containment procedures are not sufficient to contain the select agent, then the program can cite the entity for non-compliance.

COLLABORATION WITH OTHER FEDERAL PARTNERS

The CDC Select Agent Program works closely with both USDA and DOJ to implement the select agent regulations. USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for regulating the possession, use, and transfer of select agents that pose a severe threat to animal or plant health and/or animal or plant products. For select agents that pose a threat to both humans and animals or animal products, these select agents are regulated by both CDC and APHIS and are called "overlap agents". To limit the burden on registered entities, CDC and APHIS worked closely with the Office of Management and Budget to promulgate regulations with identical requirements and analogous language and to create one set of registration and reporting forms to be used by both agencies. These actions helped standardize communication and interpretation of the regulations among CDC, APHIS, and the regulated community.

To minimize the burden on entities that possess, use, or transfer select agents, a single point of contact with either CDC or APHIS was established. This single point of contact in the "lead agency" is responsible for coordinating all activities and communications with respect to the entity's registration, including coordination with both the non-lead agency (APHIS or CDC) and with DOJ. CDC and APHIS collaborate daily on select agent activities such as the development of select agent policies, resolution of common issues associated with the entity's registration (such as reviewing the required plans), conducting joint inspections, developing standard operating procedures and entity guidance documents, and providing concurrences to entities' amendments. We also collaborate on longer-term projects to improve the implementation of the select agent regulations, such as the establishment of a national select agent Web site (*www.selectagents.gov*) and development and deployment of a single shared database (the National Select Agent Registry).

CDC also works closely with DOJ's Criminal Justice Information Service (CJIS). CJIS conducts security risk assessments of all individuals and entities that request to possess, use, or transfer select agents. As of September 25, 2007, 14,868 individuals have received access approval from CDC to work with select agents, based on the results of the CJIS security risk assessments. CDC also provides information to DOJ's Federal Bureau of Investigation (FBI) for ongoing criminal investigations related to select agents.

OVERSIGHT OF SELECT AGENTS: THE CDC REGULATORY PROGRAM

CDC exerts a strong oversight role by evaluating and inspecting registered entities, in addition to providing guidance and training to registered entities.

An important tenet of the CDC Select Agent Program is that it treats all registered entities the same—whether that lab is a commercial lab, state or local public health lab, or a Federal lab (including CDC and Department of Defense labs). The Select Agent Program uses standard checklists to inspect all labs, has the same requirements of all labs, and uses the same standards when referring any lab to the HHS Office of Inspector General (HHS-OIG) for possible violations of the regulations.

CDC'S APPROACH TO INSPECTION OF ENTITIES

Laboratory inspections are the primary means by which CDC confirms compliance with the select agent regulations. Routine inspections are conducted every three years. Additional inspections are conducted any time that an entity requests a significant change to its select agent registration. Such changes may include the addition of a new facility, addition of a new agent, or the initiation of a new procedure. Other inspections that are performed include follow-up inspections based on observations from audits performed by Federal partners and investigations that may have involved biosafety or security concerns that could affect public health and safety.

CDC's protocol for routine inspections consists of an extensive review of laboratory safety and security as it relates to the possession, use, and transfer of select agents. CDC uses specific checklists to guide its inspections (the checklists can be found at *www.selectagents.gov*). These checklists have been developed from the select agent regulations and nationally recognized safety standards. The information entered on the checklists is derived from inspectors' observations of the physical safety and security components of the facility, an examination of the documentation available, and from interviews with laboratory personnel. These findings are conveyed to the institution in an inspection report. Entities must respond within a specified timeframe to the deficiencies noted in the inspection report and provide documentation of how they have resolved those deficiencies. In circumstances where the deficiencies are serious and CDC wants to confirm in person that the deficiencies have been corrected, a verification site visit is performed.

When CDC identifies deficiencies and possible violations of the select agent regulations, several types of enforcement actions can occur:

- Administrative actions: CDC can decide to suspend or revoke a registered entity's certificate of registration (a suspension can be for all work at a registered entity or be specific to particular agents or particular types of experiments). Also, CDC can deny an entity's application to possess, use, or transfer select agents;

- Referral to HHS-OIG: CDC can refer possible violations of the select agent regulations to HHS-OIG. HHS-OIG can levy civil monetary penalties (up to $250,000 for an individual for each violation and up to $500,000 for an entity for each violation) or recommend criminal enforcement (imprisonment for up to five years, a fine, or both).
- Referral to FBI: CDC can refer possible violations involving criminal negligence or a suspicious activity or person to the FBI for further investigation.

As of September 25, 2007, CDC has referred 37 entities to HHS-OIG for violation of the select agent regulations (such as for unauthorized transfers and entities that are not registered with the Select Agent Program in possession of select agents). HHS-OIG has levied $837,000 in civil monetary penalties against ten (10) of the entities. For further information, please see the HHS-OIG Web site *(http://oig.hhs.gov)*. HHS has not referred to DOJ any violations of the select agent regulations for criminal prosecution.

Technical Assistance and Guidance Provided to Strengthen the ProgramWhile enforcing the select agent regulations is the CDC Select Agent Program's primary responsibility, the program also promotes laboratory safety and security by providing technical assistance and guidance to registered entities. Some of the technical assistance that CDC provides to registered entities includes having a primary point of contact assigned to each entity, development of frequently asked questions that are posted on the program website, and technical presentations at various conferences. The CDC Select Agent Program in collaboration with APHIS provides assistance and guidance to help the entire regulated community operate as safely and securely as possible.

Some examples of the assistance that the CDC and APHIS Select Agent Programs have recently provided to the regulated community include:

- As mentioned previously, CDC and APHIS released a security guidance document to registered entities.
- CDC and APHIS released inspection checklists to assist registered entities in complying with the security, incident response, training, and recordkeeping requirements of the select agent regulations.
- CDC is further educating the entities about the regulations and the inspection process. It recently completed two training videos that explain the facility inspection process to the regulated community.

In addition, CDC has proactively worked with registered entities in advance of hurricanes to ensure that all select agents are properly secured. For example, prior to the landfall of Hurricane Katrina in 2005, CDC contacted 11 registered entities located in Louisiana, Mississippi, and Alabama. CDC collected information regarding the entities' plans to safeguard select agents during and after the storm and informed the entities that CDC stood ready to expedite the emergency transfer of select agents should the need arise. CDC has taken similar action in 2006 and 2007 in anticipation of other hurricanes and predictable natural disasters (such as floods) that could affect public health and safety, to minimize risk and any impact on public health and safety.

PROGRAM ACTIVITIES AND RESULTS

Accomplishments to Date. Since the publication of the select agent interim final rule in 2003 (followed by the final rule in 2005), CDC in collaboration with our Federal partners has (as of September 25, 2007):

- Conducted 607 inspections to ensure that appropriate security and safety measures are in place to deter the theft, loss, or release of select agents;
- Authorized 2,199 requests to transfer select agents; and
- Granted access approvals to 14,868 individuals to work with select agents, following a security risk assessment by CJIS.

REPORTS OF THEFT, LOSS, AND RELEASE

CDC investigates all reports of theft, loss, or release of select agents to ensure that the public's health and safety are protected. It is important for the public to know that after careful investigation, no incidents reported at select agent laboratories were considered to be a public health threat. From 2003 until September 25, 2007, there have been one hundred five (105) incidents reported to CDC through the Select Agent Program's theft, loss, and release reporting system. As a result of follow-up investigations conducted by HHS, USDA, and the FBI regarding these reports, it was determined that there were:

- No confirmed losses of a select agent;
- No confirmed thefts of a select agent; and
- Three (3) confirmed releases of a select agent which were identified by illnesses in five (5) lab workers that had occurred as a result of working with these agents.

Even in the best of laboratories, which follow all biosafety guidelines, accidents like a broken test tube or a needle stick can still occur, and we can expect that we will continue to receive reports of possible losses and releases of select agents. However, we believe we should always strive to eliminate all incidents. Appropriately contained and managed laboratories have multiple systems in place to ensure biosafety and have robust occupational health services in place to quickly mitigate the effect of any laboratory incident. We also believe that the security requirements put in place by the select agent regulations will continue to mitigate the possibility of a theft of a select agent.

Moving Forward with Enhancing the Select Agent ProgramThe CDC Select Agent Program has accomplished much since the program began, but we are always looking for ways to improve. The Select Agent Program is a young program and it will continue to build upon its successes and learn from its challenges. CDC is committed to continuous program improvement to fulfill its mission.

LESSONS LEARNED

Investigations of select agent registered entities have taught CDC some important lessons:

- We need improvements in our inspection process. Some of the improvements under consideration include:
- Expand the scope of interviews to include more types of laboratory workers during inspections, to better assess the implementation of policies and the quality of training;
- Examine more closely the implementation of biosafety, security, and incident response plans;
- Review a broader array of documents during our inspections, such as biosafety committee meeting minutes and occupational health records, to identify problems that may go unreported by registered entities; and
- Assess the composition of our inspection teams, the frequency of our inspections, and whether we need to apply a prioritization system to how often we inspect labs.
- We need improvements in our verification process. Whereas before we relied primarily upon documentation from entities to confirm that deficiencies were corrected, we plan to conduct more verification site visits.
- We need to provide additional outreach and training to the regulated community, including additional outreach and training to Responsible Officials and creation of additional guidance documents related to biosafety, incident response, record-keeping, and theft, loss, and release.

The CDC Select Agent Program also must address the challenge of how the select agent regulations apply to emerging technologies, such as synthetic genomics and nanotechnology. With technology advancing at a rapid pace, CDC and its Federal partners need to constantly review the select agent regulations and our implementation of the regulations to ensure that we can respond to new threats and vulnerabilities.

EXTERNAL REVIEW OF THE CDC SELECT AGENT PROGRAM

In the coming year, CDC will commission an external peer review of the CDC Select Agent Program. The external group conducting the review will actively solicit the input of stakeholders and the general public.

In addition to this external peer review, HHS-OIG is conducting an audit of CDC's management of its select agent program. We look forward to receiving the findings from that audit in 2008 and plan to carefully consider and implement HHS-OIG's recommendations.

The select agent programs at CDC and APHIS, working in concert with DOJ, have greatly enhanced the nation's oversight of dangerous biological agents and toxins. Because of the efforts of the individuals in these programs, there is improved awareness of biosafety and biosecurity throughout the select agent community. The select agent regulations have helped ensure that research with select agents is conducted as safely and securely as possible. CDC and its Federal partners have accomplished much in the few years since the publication of the select agent regulations, but we must remain vigilant in ensuring laboratory safety and security. We will continue to enforce the regulations and provide technical assistance and guidance to the regulated community to ensure that the public's health and safety are protected.

CDC greatly appreciates the support of this Subcommittee and the rest of the Congress in supporting its activities. We look forward to continuing our work with you on these important issues. Thank you for the opportunity to share this information with you. I am happy to answer any questions.

Mr. STUPAK. Thank you. Dr. Auchincloss?

STATEMENT OF HUGH AUCHINCLOSS, M.D., DEPUTY DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. AUCHINCLOSS. Mr. Chairman, members of the subcommittee, my name is Hugh Auchincloss and I am the Deputy Director of the National Institute of Allergy and Infectious Diseases, one of the National Institutes of Health.

I am pleased to have the opportunity to discuss the expansion of NIH's biodefense research infrastructure. I have submitted written testimony but will highlight certain portions in these oral remarks.

The anthrax attacks in 2001 were a sobering reminder that biologic agents can be used for terrorism. In addition, defense against naturally-emerging infections must be a top national priority. In February 2002, the NIH embarked on a systematic planning process for biodefense. We convened a blue ribbon panel made up of distinguished scientists representing academia, private industry and the Government. And we also conducted extensive discussions with other Federal agencies. Based on this input, we developed the NIAID Strategic Plan for Biodefense Research and other supporting documents. That blue ribbon panel noted that the shortage of BSL–3 and 4 laboratories was a major obstacle to accomplishing the objectives of the NIAID Biodefense Research agendas. NIAID then estimated the number of new facilities needed to accomplish our biodefense research objectives. Congress responded appropriating over $850 million for the construction of new BSL–3 and 4 facilities in four separate bills between 2002 and 2005. As a result, 14 new BSL–3 facilities and four new BSL–4 facilities are scheduled for completion within the next several years.

During the development of our construction project, we have had literally hundreds of meetings in public forums to discuss our building program, the agents that will be studied there and to keep the public well informed.

The NIH is committed to helping ensure that all biodefense research facilities operate safely with maximum protection of the public health. The safety standards for this type of research are best articulated in the Biosafety and Microbiological and Biomedical Laboratories Manual, this so-called BMBL. However, monitoring adherence to these good laboratory practices is complicated because multiple agencies are involved. You have already heard from Dr. Besser that much of the research in BSL–3 and 4 facilities involves select agents, which are regulated by CDC and other Government agencies. The NIH Office of Biotechnology Activities administers guidelines for research involving recombinant DNA and requires that Institutional Biosafety Committees, or IBCs, oversee this work at the local level. The IBCs first came into existence to oversee recombinant DNA research but many institutions have gradually broadened IBC responsibilities to include oversight of research involving all pathogens studied at BSL–3 and 4 levels. However, at this time, there is no Federal body that sets national standards or policies for this particular function of local IBCs. To enhance the effectiveness of the IBCs, as their role has evolved, the NIH has worked intensively with the IBC community through a program of outreach and education. Furthermore, each of the institutions receiving one of the new construction grants from NIAID has an IBC appropriately registered with NIH and each has willingly accepted responsibility for adhering to the BMBL standards.

NIH is looking at ways to strengthen local and Federal oversight of facilities that conduct biodefense research. Clearly, the issues associated with this oversight are much larger than the NIH or even the Department of Health and Human Services. Biodefense research is conducted by many Government agencies. For that reason, the Department of Health and Human Services, the United States Department of Agriculture, the Department of Homeland Security and the Department of Defense have already agreed to establish a trans-Federal task force to undertake, in consultation with other relevant agencies, an intensive analysis of the current biosafety framework and to develop a set of recommendations for improvement.

Given the importance of biosafety for the country and its citizens, active participation from the public at large will be essential.

The planned expansion of our infrastructure is needed if we are to fulfill our research agenda and protect the Nation from disease threats, be they deliberate or acts of nature. We have already made substantial progress in ways that I have outlined in my written testimony. Progress can occur more rapidly as the new facilities become available.

Thank you very much and I will be happy to answer questions also.

[The prepared statement of Dr. Auchincloss follows:]

STATEMENT OF HUGH AUCHINCLOSS, M.D.

Mr. Chairman and members of the Subcommittee, my name is Hugh Auchincloss and I am the Deputy Director of the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). I am pleased to have the opportunity to discuss the NIH biodefense research program, including the expansion of the Nation's biodefense research infrastructure and the need to ensure that biodefense research is conducted safely.

The anthrax attacks in 2001 were a sobering reminder that the threat of deliberately released microbes can be used as a form of terrorism. Moreover, naturally occurring microbial outbreaks pose a serious threat to domestic and global health. The experience with SARS in 2003 and the ongoing outbreaks of H5N1 avian influenza and extensively drug-resistant tuberculosis have reminded us that defense against naturally emerging microbes must be a top national priority. Congress has recognized the urgency of improving our defenses against emerging public health threats and has supported funding for such research. Within the broad Federal effort against emerging threats to public health, the role of the NIH is to conduct and support basic and applied research that will lead to new vaccines, drugs, and diagnostic tools.

EXPANDING THE NATION'S BIODEFENSE RESEARCH CAPABILITY

In February 2002, the NIH embarked on a systematic planning process for its biodefense research program. It first convened the Blue Ribbon Panel on Bioterrorism and Its Implications for Biomedical Research, made up of distinguished scientists representing academia, private industry, and government. Based on the panel's advice and extensive discussions with other Federal agencies, the NIH developed three key documents to guide its biodefense research program: the NIAID Strategic Plan for Biodefense Research, the NIAID Research Agenda for Category A Agents, and the NIAID Research Agenda for Category B and C Agents.

As a result of the strategic planning process, a clear consensus emerged that meeting the goals of the biodefense Research Agendas would require additional research infrastructure, especially research laboratories built to modern Biosafety Level 3 (BSL–3) and Biosafety Level 4 (BSL–4) standards. BSL–3 laboratories are used to study contagious agents that can be transmitted through the air and cause potentially lethal infection. BSL–4 laboratories are used to study agents that pose a high risk of life-threatening disease for which no vaccine or therapy is available; they incorporate all BSL–3 features and occupy safe, isolated zones within a larger building.

There has been considerable discussion of how best to assess the extent of high-containment facilities that would be required in the United States in the public, academic and private sectors and for what purposes these varied facilities are used. Published estimates range from as few as 200 to as many as 1400 BSL–3 laboratories. (Many institutions maintain multiple facilities.) The explanation for this wide discrepancy is that an assessment of laboratory capacity depends on the definitions and sources of information used. Estimates at the high end, for example, include the many hospitals that maintain small areas that meet BSL–3 standards that can be used for testing clinical samples that might contain infectious agents. These are not "research laboratories." Some hospitals, pharmaceutical companies, biotechnology firms, private reference laboratories and State public health laboratories also have facilities that meet BSL–3 standards, but these are not generally available for NIH-sponsored research. Finally, many BSL–3 facilities constructed before the mid–1990's cannot support research on select agents and on associated animal models. In 2002, NIAID determined that very little usable BSL–3 or BSL–4 research space was actually available for its academic scientists in the extramural research program.

The Blue Ribbon Panel of 2002 noted the shortage of BSL–3 and BSL–4 laboratory space as a significant rate-limiting obstacle in accomplishing the objectives of the NIAID Biodefense Research Agendas. In response, NIAID estimated the new BSL–3 and BSL–4 facilities that would be required to accomplish the Research Agenda. Congress also recognized the critical need for new BSL–3/4 laboratories and responded quickly to supply the necessary resources to fulfill this need. In 2002, the Department of Defense and Emergency Supplemental Appropriations for Recovery from and Response to Terrorist Attacks on the Unites States Act, Public Law (P.L.) 107–117, appropriated $70 million for the construction and renovation of NIH intramural biocontainment facilities. The Consolidated Appropriations Act of 2003, P.L. 108–7, provided $372.6 million to NIAID for construction of extramural biocontainment facilities and $291 million for construction of additional intramural biocontainment facilities. Further, the Project BioShield Act of 2004 (P.L. 108–276), amended the Public Health Service Act to provide ongoing authority to NIAID to award grants and contracts for construction of research facilities. An additional $150 million was appropriated for NIAID in the 2005 consolidated appropriations act (P.L. 108–447) for extramural facilities construction grants.

The NIH is now implementing a construction program that will complete 14 new BSL–3 facilities and 4 new BSL–4 facilities within the next several years. During this process, the NIH or its funded institutions have participated in literally hundreds of public forums on the nature and safety of the new facilities, and have submitted reports to Congress annually, along with periodic updates on our strategic plans. In addition, NIH leadership has discussed the infrastructure expansion with Congress on many occasions. And because NIH does not fund or conduct classified research, the title and substance of every research project funded by the NIH is publicly available.

Another important aspect of the biodefense research infrastructure is a network of ten NIH-funded Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCEs). Created in 2003, these multidisciplinary academic research programs are located at institutions across the country and provide the scientific expertise for a wide-ranging biodefense research program, directed against deliberate and naturally-occurring threats, that will be pursued in the new facilities.

NIH ROLE IN ENSURING SAFETY

The NIH is committed to helping ensure that all biodefense research facilities provide maximum protection for public health. The NIH is committed to the highest quality in the design and construction of these facilities, the rigorous training of the personnel that operate them, and the safe conduct of the research undertaken within them.

To ensure that the new laboratories are designed and constructed to the highest standards, the NIAID works closely with each grantee institution. Highly experienced NIAID staff architects and engineers, with extensive experience in design of biocontainment facilities, are assisted by a Construction Quality Management group of contracted consultants with additional expertise. Together, these teams make certain that the finished projects will meet the regulations of HHS's Centers for Disease Control and Prevention (CDC) and the Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS) for facilities that conduct research on select agents.

The NIH also supports a vigorous biosafety and biocontainment training effort that has expanded substantially over the past five years. The National Biosafety and Biocontainment Training Program (NBBTP) is a partnership between the NIAID and the NIH Division of Occupational Health and Safety (DOHS), managed by a not-for-profit education and research foundation. The mission of this program is to prepare biosafety and biocontainment professionals of the highest caliber. The program offers two-year post-baccalaureate and post-doctoral fellowships at NIH's campus in Bethesda, Maryland, with both academic and hands-on training. The NBBTP has also provided training for containment laboratory operation and maintenance personnel across the country. In addition to this program, NIAID funds 28 Institutional Training Grants in Biodefense, and the RCEs conduct extensive training in biosafety and biocontainment. At the RCE at Emory University in Atlanta, for example, trainees from across the country regularly participate in BSL–3 and BSL–4 training in mock laboratories, constructed specifically for training purposes.

When these new facilities are ready for operation, NIH is committed to ensuring that the research conducted within them is performed safely. The most widely used guidance on the safe conduct of this research is the Biosafety in Microbiological and Biomedical Laboratories Manual (BMBL), which was first produced jointly in 1984 by the NIH and CDC and which is now in its fifth edition and available online.

Monitoring adherence to good laboratory practices is a complex process because multiple agencies are involved. Much of the research in BSL–3 and BSL–4 facilities involves pathogens that have been designated as select agents. CDC and APHIS have the responsibility for regulating the possession, use, and transfer of select agents. For research that involves recombinant DNA, the select agent regulations incorporate the NIH Guidelines for Research Involving Recombinant DNA Molecules (Recombinant DNA Guidelines) as a consideration in the entity's development of its biosafety plan. The NIH Office of Biotechnology Activities (OBA), with advice and guidance from the NIH Recombinant DNA Advisory Committee (RAC), is responsible for implementation of the Recombinant DNA Guidelines, which outlines biosafety and containment standards for research involving recombinant DNA. Also, the select agent regulations require that restricted experiments, such as the deliberate transfer of a drug-resistant trait to a select agent, must be approved by CDC or APHIS prior to initiation. However, some research conducted in BSL–3 facilities involves neither select agents nor recombinant DNA.

Local institutional bodies play a very important role in oversight of many aspects of biomedical research. For example, oversight to protect human subjects in clinical studies is provided by local Institutional Review Boards (IRBs), and in the case of animal research, oversight to ensure humane treatment is provided by the Institutional Animal Care and Use Committees (IACUCs). The NIH Guidelines mandate that Institutional Biosafety Committees (IBCs) oversee recombinant DNA research, but many institutions have gradually broadened IBC responsibilities to include oversight of research involving all pathogens studied at BSL–3 and BSL–4 levels. At this time there is no Federal body that sets national standards or policies for this function of local IBCs, and adherence to BMBL guidelines for BSL–3 and BSL–4 research is voluntary; however, the select agents regulations require regulated entities to comply with the BMBL guidelines or equivalent standards.

The NIH is deeply concerned about recent reports of accidents occurring in BSL–3 facilities. When these events involve recombinant DNA, they are reported to the OBA, and a root cause analysis is done so that NIH can assess the adequacy of the institution's response and work with the institution to put mechanisms in place to mitigate the chance of a reoccurrence. To enhance all of the functions of the IBCs, the NIH has worked intensively with the IBC community. These efforts have included an extensive program of outreach and education, involving frequent day-long training sessions, exhibits at major scientific conferences, policy guidances, educational resources for institutions to use in local training, and other means. Furthermore, each of the institutions receiving one of the new facilities construction grants from NIAID has an IBC appropriately registered with NIH and each has willingly accepted responsibility for adhering to BMBL standards.

The NIH is examining ways to strengthen local and Federal oversight of facilities that conduct NIH-funded research. The issues associated with oversight of research in BSL–3 and BSL–4 facilities transcend the NIH, or even the HHS. Biodefense research involving BSL–3 and BSL–4 facilities is conducted by many government agencies, including the Department of Defense (DoD), the Department of Homeland Security (DHS), and the USDA, as well as by universities and biotechnology companies. As I noted earlier, BSL–3 facilities exist in hospitals for routine handling of clinical samples. It is important to devise a framework that improves oversight, training, and reporting to enhance safety without causing unintended negative consequences for either patient care or the biodefense research program. For that reason, HHS, USDA, DHS, and DoD have already agreed to establish a Trans-Federal Task Force to undertake, in consultation with other relevant agencies, an intensive analysis of the current biosafety framework and to develop a set of recommendations for improvement. Given the critical importance of biosafety to protecting public health and the concerns that the high containment facilities engender among local communities, active participation in this process from the public at large will be essential.

Support for infrastructure for biodefense research is essential if we are to fulfill our biodefense research agenda and protect the Nation from disease threats, be they deliberate or acts of nature. We have already made substantial progress with the facilities now available. For example, NIH-funded scientists have developed a safer second-generation smallpox vaccine called ACAM2000 and a very promising new smallpox drug named ST–246. Investigators have developed and tested a new anthrax vaccine called rPA and have achieved promising results with antibodies capable of neutralizing anthrax toxins. They have developed first- and second-generation vaccines against Ebola virus, and investigated a promising Ebola therapy based on RNA interference. These and many other advances required the use of containment facilities of the type that are now under construction. Progress should occur more rapidly as the new facilities become available.

NIH-funded biodefense researchers are acutely aware of the threat posed by the pathogens they study. These experts understand the need to handle them with utmost care, the need for rigorous training and state-of-the-art equipment, and the need to scrupulously follow all required procedures. Their awareness also includes a deep understanding that the Nation's biosecurity depends on their work, which is the conduct of research that will lead to new tools essential to meet emerging and re-emerging threats to public health.Thank you for this opportunity to discuss this very important issue with you. I will be happy to answer questions.

Mr. STUPAK. Thank you. Captain or Dr. Chosewood, an opening?

Dr. CHOSEWOOD. No.

Mr. STUPAK. OK. We will go to questions.

Dr. Besser, if we can start with you please. There is a thing called restricted experiments, right, which pose extraordinary risks?

Dr. BESSER. Yes, sir.

Mr. STUPAK. And you have to apply for a permit to do these restricted experiments?

Dr. BESSER. That is correct.

Mr. STUPAK. Where are these restricted experiments carried out, at level 3 labs or level 4 labs?

Dr. BESSER. Yes, they are conducted in select agent laboratories, primarily at level 3 and 4.

Mr. STUPAK. OK. And how many applications do you receive for these restricted experiments on an average each year?

Dr. BESSER. Approximately five or six.

Mr. STUPAK. Five or six. If these are restricted experiments or the ones that impose extraordinary risk and if you only get five or six of these, why would we want to increase all these labs then?

Dr. BESSER. When you look at the breadth of work that takes place in select agent laboratories, it is a very small part of that work that would be classified as a restricted experiment. The vast majority of the work does not fall within the category of restricted experimentation.

Mr. STUPAK. OK. Well, before 2001, we had three of these labs, level 4 labs, we are now up to 15. How many labs do we need at level 4?

Dr. BESSER. We are at the anniversary of that anthrax attack and at that time I was in Boca Raton working with the FBI investigating that outbreak. I spent 2 weeks in the Winnebago with them. And during that time, I can tell you that we were pretty scared about our ability to deliver countermeasures to people who might need them.

Mr. STUPAK. OK. But how many labs do we need, or do we need more Winnebagos?

Dr. BESSER. I can tell you based on my experience in that event and my experience previously as head of the branch at CDC that does anthrax work, that there was a limitation on our ability to develop countermeasures based on the number of labs. I cannot tell you though how many labs we need.

Mr. STUPAK. But to develop countermeasure does not mean necessarily more labs, right?

Dr. BESSER. Well, when you look at what it takes to develop a countermeasure, these measures need to be tested and much of that work, in terms of testing, requires animal testing. That type of work does require high-containment laboratories.

Mr. STUPAK. OK. Dr. Auchincloss, let me ask you then because you said you have the distinguished panel. There was strategic planning of the three or four level labs and you indicated there were not enough labs.

Dr. AUCHINCLOSS. That is correct, sir.

Mr. STUPAK. So did the panel recommend how many labs we needed then?

Dr. AUCHINCLOSS. The panel recommended a research agenda. It did not recommend, specifically, the number of new facilities that would be needed.

Mr. STUPAK. Would the research agenda then dictate the number of labs we need in this country?

Dr. AUCHINCLOSS. The research agenda was what we used to determine the number of new facilities needed in the country.

Mr. STUPAK. OK. So you used the research agenda to determine the number of labs we need in this country. Is that what you said?

Dr. AUCHINCLOSS. That is what I said.

Mr. STUPAK. So how many level 3 labs do we need in this country?

Dr. AUCHINCLOSS. We determined, on the basis of that research agenda, that between 10 and 15 BSL–3 facilities were needed for the extramural community.

Mr. STUPAK. Ten to 15.

Dr. AUCHINCLOSS. And at least two level 4 facilities for the extramural community.

Mr. STUPAK. OK. We had three. We are now up to 15. So it should be five, so we got 10 too many level 4 labs?

Dr. AUCHINCLOSS. Sir, the estimates that the NIH has put together refer to the needs for the scientists that the NIH funds.

Mr. STUPAK. Sure.

Dr. AUCHINCLOSS. And we are not trying to claim that our planning applies to other Government agencies or other funding agencies.

Mr. STUPAK. So you only want five labs total then to do what NIH wants to do?

Dr. AUCHINCLOSS. NIH determined that it needed between 10 and 15 BSL–3 facilities.

Mr. STUPAK. Right. And two more level 4.

Dr. AUCHINCLOSS. And two level 4 for the extramural community.

Mr. STUPAK. Correct.

Dr. AUCHINCLOSS. And then we actually determined that we have two additional level 4 facilities for the intramural program that can be worked.

Mr. STUPAK. So your scientific panel only looked at what NIH's needs were.

Dr. AUCHINCLOSS. Our scientific panel only looked at what the NIH research agenda would be.

Mr. STUPAK. Did CDC do the same things, take a look at what you thought was necessary?

Dr. BESSER. No, sir. CDC looked at its own needs in terms of the work that we do in diagnostics and that lead to the expansion at CDC in our level 4 capabilities.

Mr. STUPAK. OK. So the CDC then determined you needed so many level 4 for your work you do in this area?

Dr. BESSER. That is correct.

Mr. STUPAK. And how many is that, level 4 labs?

Dr. BESSER. Four additional laboratories at CDC.

Mr. STUPAK. Four more additional labs at CDC. So it looks like every agency is making their own assessment and doing their own thing basically, right?

Dr. BESSER. I think that there is room for a more comprehensive look at our national needs in both of these areas.

Mr. STUPAK. Well, if you got 15 different agencies, was your other testimony, you are up to four. If we did five, four at each one, four times 15 is 60. We would need 60 more level 4 labs if every agency did their own assessment. Is anyone in control ball? Who should be in control? It sounds like CDC, in your testimony, Dr. Besser, are the ones who do the protocol; you are the ones that do the inspections. Should you be in charge of all the labs of all the agencies?

Dr. BESSER. I think that the process that Dr. Auchincloss referred to in his oral statement of pulling together an intra-governmental group, pulling together a blue ribbon panel to look at the activities in BSL–3 and BSL–4 facilities will help to address that issue. I think that CDC is effectively executing its mission around the select agent program. But as we have heard, that does not cover all of the organisms that need to be handled safely and securely in laboratories.

Mr. STUPAK. Well, let me ask this. It seems like from where I am sitting, over a billion dollars have been spent on labs that we know of. No one can tell me how many labs that we have, the quantity of stuff we are looking at, the quality of stuff we are looking at that could be a threat to this country. It seems like if we put the money out there then germs will come, so we will build these labs. I mean, what has really changed since the fall, other than anthrax, OK? Other than that, what has really changed that would require this proliferation of labs that agencies double and triple in labs they have. Is there a greater threat to us? If so, should we not be putting the money into research as to most all labs? So what has changed in the last 5 years, other than more money available? Can someone answer that?

Dr. BESSER. I will start and you can follow. I think 2001 was a wake up call; and it was a wake up call in terms of anthrax. But it was a wake up call beyond that and it forced a look at what are the potential agents that could be used deliberately and what are our abilities to respond with either vaccines or treatments for those conditions. That lead to issue of legislation and a push to develop countermeasures.

Mr. STUPAK. True.

Dr. BESSER. But as part of that, there was a move to expand the laboratory capability to be able to address those needs. In addition to that, if we look at our overall preparedness efforts around the country, there has been developed something called the Laboratory Response Network, which is not doing research but it does have BSL–3 capabilities in order to be able to rapidly diagnose these type of serious infections we are talking about to allow communities to respond faster. We are now at a point where 90 percent of the U.S. population lives within 100 miles of one of these facilities and it has created, I think, a laboratory infrastructure that is critical to our preparedness and response.

Mr. STUPAK. But preparedness would be a countermeasure, a medical countermeasure to like anthrax. Have we seen any counterterrorism, medical counterterrorism measures to defeat anthrax. We still have not determined the strain from 2001, according to the last panel, as the one that killed five people and sickened 20 others.

Dr. BESSER. There has been a lot of work done in the area of anthrax, vaccine work and countermeasures. CDC has undertaken a study looking at the existing anthrax vaccine to try and reduce the number of doses that are required to confirm protection. In addition, NIH has supported extensive work in developing vaccines for anthrax that might be much safer.

Mr. STUPAK. When was the last time you updated the selected list, the selected agents?

Dr. BESSER. The last time was August 28 of this year. We published in the Federal Register and it is still open for comment, the latest revisions to the select agent list.

Mr. STUPAK. Is SARS going to be one of these select agents?

Dr. BESSER. SARS was considered by the committee. If I could explain the process by which agents are considered? There is an intergovernmental committee called the ISATTAG. That is the Intergovernmental Select Agent and Toxin Technical Advisory Group. It contains representation from all the Federal agencies that do work with select agents: CDC, NIH, FDA.

Mr. STUPAK. This group met in August this year. When did it meet before August of this year?

Dr. BESSER. Well, the notice went out in August.

Mr. STUPAK. OK. They met this year. When did they meet before this year?

Dr. BESSER. The ISATTAG not only reviews the select agent list for our program, but they also review proposals for restricted experiments, as was discussed earlier. And the ISATTAG meets on an ad hoc basis, typically four or five times a year as needed when issues come up.

Mr. STUPAK. OK. Now, getting to the issue asked about SARS.

Dr. BESSER. No, select agents.

Mr. STUPAK. OK. You met four to five times. SARS is a select agent. The hantavirus is not a select agent. And there is one other, dengue fever. These are all we have no cure for. If they break out, people can die.

Dr. BESSER. Right.

Mr. STUPAK. It seems like you are building the labs but no one is doing anything about getting a list and trying to restrict the research of the most dangerous things that could cause most harm to us and spend, what, 5, 6 years.

Dr. BESSER. Each of those agents has been considered and was not included on the list. There are 14 criteria that are looked at when considering an agent for the select agent list. When the SARS epidemic first occurred and we knew very little about that virus, it was being handled in BSL–4 facilities. When the ISATTAG looks at the science around an agent and whether it should be considered a select agent, we look at the degree of pathogenicity, how bad an infection does it cause, how easy is it to transmit person-to-person, how easy is it to spread within a community, what is the route of exposure, how stable is it in the environment, how easy would it be for somebody to produce that agent, can it be genetically manipulated or altered because there are long term——

Mr. STUPAK. SARS does not make it then?

Dr. BESSER. Well, SARS did not make it to that list and if you——

Mr. STUPAK. Since the fall of 2001, have you added any more agents to this select list? Select list first came out, what, in 1996?

Dr. BESSER. Yes. In October 2005.

Mr. STUPAK. How many have you added since the fall of 2001?

Dr. BESSER. The 1918 influenza virus was added in October 2005.

Mr. STUPAK. OK. We had flu. Did you add anything else? I am trying to justify all this money and all these labs. If we have a select agent list in 1996 at 72 and we add one, we get up to 73 maybe; how do we justify a proliferation of all these labs?

Dr. BESSER. Well, the work being done in those laboratories is not necessarily being done just on the new agent, 1918 flu. But it is acknowledging the lack of work or the need for work with some of the existing agents.

Mr. STUPAK. Correct. And Congress' charge was to develop countermeasures to make America safe. And if the list has not grown more agents that we should be concerned about but yet we have probably 10 times more labs than we had before then. Again, it goes back to look like we are building labs and hoping the germs will come. That is my concern. Mr. Green for questions.

Mr. GREEN. Thank you, Mr. Chairman. When you let off by asking how many Winnebagos we need, our colleague, Mike Ross on our committee keeps talking about all those FEMA trailers we have in some field in Arkansas. Maybe we can put wheels on them and get them. I thank our panel for being here and appreciate your work. Coming from Texas, we certainly have been following the news accounts on instances in the Texas biosafety labs. One of the news articles quotes a laboratory expert who compared lab settings to hospital settings and noted that infections are not entirely unexpected. Generally, where are the risks in this line of work and would you say that they are primary to the lab worker or would it be to the broader community?

Dr. CHOSEWOOD. Obviously, we are concerned about infections or releases in any setting because safety is a vital component of all laboratory work for certain. The vast majority of incidents that have occurred and given the vast amount of work that has gone on, we believe that the actual number of events is very small. But when those events have occurred, they have affected primarily the laboratory workers. The select agents folks can give you some specific numbers on the amount of workers who have acquired infection. But the risk to the environment, in all of those cases, has been non-existent in our opinion.

Mr. GREEN. OK. Another course of questions of safety are of utmost concern, but I also want to make sure that we have a measured and thoughtful reaction to the incidents we hear about. Of course, we want 100 percent safety but based on the incidents to date, the expert indicated that he was not certain the problems reached the level of a crisis. Can you share your thoughts on that issue, and would you agree or disagree with that statement whether it had reached that level of crisis?

Dr. BESSER. I think it is critically important that we move forward very quickly to convene an intergovernmental group and look at a process for reviewing how lab safety oversight is now provided and we are committed to doing that. I think that the work of this committee in shedding light on issues about safety will help move the entire field forward and we welcome an opportunity to see the GAO report and the preliminary report and their recommendations because I think that as a young program, there is a lot we can learn and there is a lot we can do to improve our oversight.

Mr. GREEN. Well, I know our Oversight and Investigation Subcommittee, we do not do legislation but typically will refer to our the committee's Health Subcommittee, for example, and I look forward to working with you and I know our full committee does. Based on the incident reports received by the CDC, what is the primary source of the incidents in the biosafety labs? Can you attribute it to accidents, the human or engineering design flaws?

Dr. BESSER. The vast majority of events involve human error. That is why it is so important that individuals, like your daughter, are well trained if they are going to be working in a laboratory; that they have the right equipment for the type of experiment that they are doing; that that experiment has been designed to minimize the amount of risk; and that their engineering controls, in case that individual makes an error, it does not get outside of the laboratory.

Mr. GREEN. OK. Our GAO witness mentioned the CDC biosafety microbiological and the biomedical laboratories guide, as well as the importance of training lab staff. Specifically, Dr. Rose mentioned that BMBL's guidelines that personnel must receive training on potential hazard and precautions. Can you elaborate on that training guideline? Is there a mandate for that guideline for level 3 and 4 or is it to all the levels of these labs?

Dr. BESSER. You want to comment on that, Dr. Weyant?

Dr. WEYANT. With respect to the regulated select agent community, select agent laboratories are required to have a biosafety plan, along with a security plan and an incident response plan. They are required to train their staff in accordance with these plans and they are also required to perform drills on an annual basis. As part of our inspection regime through the CDC select agent program, we review training records when we inspect entities.

Mr. GREEN. OK. I would like to carry forward and since I am almost out of time, Dr. Weyant, I am interested in clarifying the type of agents that are being researched in the BSL–3 and BSL–4 labs. Our witness on our fourth panel has referred to these agents as biological weapons agents. A term that certainly elicits strong reaction from the public. My understanding, however, is that these are not actually weapons agents by definition, rather they are infections agents occurring naturally in nature. Is it fair to assume that the BSL–4 labs are necessarily working on biological weapons agents and can you clarify the distinction of the two?

Dr. WEYANT. Well, it depends on usage. An agent such as bacillus anthracis, the agent that causes anthrax, exists in the environment. It exists in soil in many parts of the world. However, the agent can be grown up and purified and weaponized as was demonstrated in the events beginning October 4, so it is difficult to take a single organism on this list and say it is absolutely a weapons agent or it is absolutely a naturally-occurring agent. I would say it is fair to say that for the agents listed on this list, it is possible that they could be both.

Dr. BESSER. If I could add to that.

Mr. GREEN. Please.

Dr. BESSER. Currently CDC is assisting States on investigation of cases of anthrax in Connecticut, cases of botulism in the Southeast, cases of tularemia in the Southwest. These are all agents that are select agents and it is important that they have laboratories that can diagnose those. But in their naturally-occurring form, they are not something that could readily be used in a biological attack. But in these laboratories we can learn about those agents and we can work to improve our diagnosis, which is critical, and help to develop treatments.

Mr. GREEN. OK. Thank you, Mr. Chairman.

Mr. STUPAK. But in response to that last question, especially on botulism, the FDA's response was that it closed down six of their 13 labs.

Mr. GREEN. I think those make sense, which was just said.

Mr. STUPAK. Botulism. If we are going to find it, FDA has responsibility but they want to close six of the 13 labs. Should not we add food safety to CDC then?

Dr. BESSER. There are different roles in FDA. We have a primary role in terms of investigating outbreaks related to botulism and distributing the botulism antitoxin. And to succeed in that mission, we have to ensure that we have rapid diagnostics. Currently, our laboratories at CDC are working on a new ELISA test, which is rapid test for diagnosing botulism that will have natural applications, as well as applications if there were deliberant events.

Mr. STUPAK. Right. I do not disagree with you with that last statement but if the FDA, who is responsible for it, is closing the labs and you guys are opening more labs, it seems like the agencies—no one is in charge here. Everyone is doing their own thing. With that, let me turn it over to Mr. Burgess for questions please.

Mr. BURGESS. Thank you, Mr. Chairman. I apologize for being out of the room for a while. I know I pledged to you earlier today that I would not desert you through this hearing and my State delegation called and they actually rank a little higher than you, Mr. Chairman. Let me just follow up and listening to the chairman's questions, Dr. Besser, in the room outside, on the select list, the select agent list, that is developed, SARS is not on that list. Is there a downside to having an agent on that list? Does it in any way inhibit research, inhibit the evaluation of the agent? Is there a research-oriented reason not to put an agent on that list? Is it going to make it more difficult for the scientists to do their job? And actually, whoever feels that they can answer the question. Dr. Weyant, that is fine.

Dr. WEYANT. Thank you, sir. Yes, there is a downside to doing work in a highly-regulated environment. There are extensive record keeping requirements that we have for select agent laboratories. There are extensive security requirements. As was discussed earlier this morning, individuals who apply to work with select agents have to undergo a Department of Justice security clearance procedure, whereas individuals that would not work on a select agent, do not have to undergo that. So there is a downside to working in a highly-regulated environment. There is a lot more paperwork and it is more resource intensive.

Mr. BURGESS. I referenced SARS earlier because of the rapidity with which you guys, all of you at the table, made the designation of a coronavirus previously reported and causing human disease, came from a remote area in China, spread on planes from people coming over here. Really relatively unsophisticated tools that beat back the threat of this epidemic and I do not want to see us, Mr. Chairman, do anything on this committee that would rob us of that ability and I cannot say that anyone new going into that epidemic that we are going to be able to beat this with epidemiology and quarantine. But at the same time, because of the work that you do, the scientific ground work that you did early on in that investigation, lead you to the conclusion that we have tools on a shelf that we can beat this with and they, in fact, are the same tools that were available in 1918 and let us get busy and do them.

In fact, I was really concerned, not to pick on the CDC but you guys had a scientist get sick over in China; and he got put on a Lear jet and brought back over to this country and I think refueled two or three times coming back over here. I called the CDC back in 2003 very concerned about is this the best way to be handling a suspected case of SARS, putting them on an airplane with the recirculating air that is present on an airplane, worrying about the exposure to people, perhaps the ground based operators who would be involved in refueling that plane and doing it for service that was required at the various stops it made back to this country. It turned out the scientist did not have SARS.

While I appreciate your dedication to bringing one of your own back who was ill, I must admit I was terribly concerned. Turns out that that concern was misplaced. Again, I just do not want us to do anything that undermines your ability to do your job because often times you do not know what it is you are going up against and you are literally walking across a bridge as you are building it. And we just have to be very careful that we do not stymie that creativity and that ability to respond. But that does lead me to the question that I asked the previous panel before and if you wanted to place us on a continuum of exposure to safety, obviously we were at one place in 2001 when the anthrax attacks on the Senate occurred, have we moved on that continuum forward or back in the 6 years that have passed since that time?

Dr. WEYANT. I think we have moved forward and I think we have moved forward because we now have a program in place that is really requiring a lot of laboratories that are working on select agents. The area of select agents, as has been said, does not cover the full spectrum of germs that can be harmful. But we did not have in place a program that required a detailed background check for individuals who work with these agents. We did not have a program that required approval and required inspections, that required documentation of safety, as well as security methods. So that is an improvement. There is a lot more that can be done and this process of this committee is raising really important issues that we need to address. I can tell you about the CDC's ability to move people who are potentially infectious has improved. By early spring, we will have a self-contained biocontainment unit that we will fit in the CDC plane that will allow for transport of a passenger safely. Again, it is critical, especially when we do not know what we are dealing with, like the beginning of the SARS epidemic, that we are able to use engineering controls to protect the public.

Mr. BURGESS. True. Well, that is very reassuring to hear that. Mr. Chairman, I just also have to mention, last year when I was taking a trip to Iraq, I think it was one trip with Mr. Green and I took a side trip to Geneva to visit what was going on with the World Health Organization. At that time, we were all real concerned about the bird flu. And CDC had their people on the ground in Geneva, in the, I do not know what you call it, the whatever it is, the biologic room, and it is an impressive amount of work. And that is impressive protection provided by American scientists on loan to the World Health Organization. Not the World Health Organization, directive of the CDC but American scientists on loan. And they went through the day's reports with me. It was absolutely astounding the breath, the scope, the danger that people were in having to go to remote areas and ferret out the symptoms that had come to their attention that might be indicative of something much more serious. So, Mr. Chairman, unless we get too complacent or smug up here that these are not real illnesses, real issues, I mean, these guys are on the front line and I believe they are committed to doing a good job. I just want us to be able to give the tools, deliver the tools to them that they need.

Mr. STUPAK. Dr. Besser, on your page four of your testimony the statement is made that the NIAID estimated the new BSL–3 and BSL–4 facilities would be required to accomplish the research agenda. Our committee has asked for a copy of that assessment. When will you provide that copy of the assessment?

Dr. BESSER. We will work with your committee to provide that as soon as we can.

Mr. STUPAK. Yes, but we would have liked it before the hearing, that is why I am asking, so get it to us, OK?

Dr. BESSER. Yes, sir.

Mr. STUPAK. All right. Second, let me ask you this question. When you are working with SARS, as has been brought up, bird flu to plague or Ebola, safety should be paramount. Do you feel that the community where these labs are located and first responders in these communities should be notified of what agents are being studied at those labs?

Dr. BESSER. I think that is an important question and I think it is critically important that communities are aware that laboratories are in their community, that they have been engaged as part of the decision as to whether a laboratory is being placed. When it comes to specifics about what agents are in the laboratory, I think that is a difficult question and one that is hard to answer. There is the importance of transparency but there is also the issue of letting individuals who may want to do harm know where certain agents are located and both of those have to be weighed.

Mr. STUPAK. OK. So you said, well, they should know about the lab but not necessarily the agents being studied there. But should the public then be made aware or notified of the shift of a lab from a level 3 to a level 4, like you may be doing down in Bethesda? Should that community be made known that it is going to go from a level 3 to a level 4?

Dr. BESSER. I think that is an important question. I am looking forward to guidance on some of these issues from our review process. I think that we have to weigh the issue of sharing information that could do harm to a community versus being open about what is going on. And I think that the more trust that the community has that the labs are being run safely, the less that is an issue. But I do not think that we are where we need to be in terms of that level of trust.

Mr. STUPAK. You think we are there at the level of safety?

Dr. BESSER. I think that the laboratories that are being built, these state of the art laboratories, are extremely safe. That does not mean that an error will not occur.

Mr. STUPAK. Yes, your own CDC lab in Atlanta was supposed to have redundancy in the electricity event when the lightening stuck. Everything shut down in a level 4 lab. You did not have the redundancy that was required and that is a brand new lab.

Dr. BESSER. Dr. Chosewood?

Dr. CHOSEWOOD. Sure. I would love to comment on that. In fact, we believe that the GAO findings about the lack of redundant power is absolutely incorrect.

Mr. STUPAK. It is incorrect?

Dr. CHOSEWOOD. Yes, sir.

Mr. STUPAK. You should have just one power source at a level 4 lab, is that what you are saying?

Dr. CHOSEWOOD. No, but in fact, that is not the case. The power outage in our building 18 laboratory occurred as a result of an error.

Mr. STUPAK. A lightning strike, right?

Dr. CHOSEWOOD. A lightning strike to the building.

Mr. STUPAK. Yes.

Dr. CHOSEWOOD. And unfortunately, the lightning protection system in that building had been interrupted by ongoing construction nearby. And so the power failure in that instance was completely appropriate. It was as if you were having a power surge in your own home.

Mr. STUPAK. So you think——

Dr. CHOSEWOOD. And if that were the case——

Mr. STUPAK. Power outages at level 4 labs are certainly appropriate?

Dr. CHOSEWOOD. No, I did not say that. One of the things that I think is important is to imagine a power surge in your own home and you have a breaker that trips appropriately. That is exactly what occurred in this situation. And that is what you would want.

Mr. STUPAK. The backup system cable was cut, was not it?

Dr. CHOSEWOOD. This was an interruption of the lightning protection system but not the backup cable for power.

Mr. STUPAK. So then why did not the back up one come on then?

Dr. CHOSEWOOD. Because it was not supposed to in an overload situation like a lightning strike. So basically at the time of the lab—we should tell you that we had no active work going on. The maximum containment labs in building 18 are actually not functional at this point. But even if they had been functional, there are multiple systems of safety in place to avoid escape of any dangerous pathogens.

Mr. STUPAK. But if you do not have any power, those backup systems are not going to work.

Dr. CHOSEWOOD. No, I would disagree because the facilities are designed to withstand higher levels of containment than the typical space. These are pressurized areas. If you have a power loss in a maximum containment laboratory, the actual air flow goes neutral, it does not become positive. You do not have the escape of that air in the lab to the outside.

Mr. STUPAK. OK.

Dr. CHOSEWOOD. Backup power is important. It is a critical thing but that was not the case here and our laboratories do have backup power.

Mr. STUPAK. Well, GOA tends to disagree with all you said but that is the information we have to work with, to share information with us and then maybe we can get some of this squared away. You mention audits. Let me just ask about an audit. Do you do any surprise inspections of these labs? Do they know when you are coming to inspect the labs?

Dr. WEYANT. The select agent regulations give us the authority to do surprise inspections.

Mr. STUPAK. Yes, but you do it?

Dr. WEYANT. As a rule, we do not do surprise inspections.

Mr. STUPAK. Well, if they know when you are coming, it is pretty easy to pass inspection. Is that what happened at A&M? You guys were right there, you guys approved everything, some minor things were out of hand and if it wasn't for this Sunshine Project, we never would have found out about the instance there, right?

Dr. WEYANT. Yes, I think the issue of unannounced inspections is something we need to consider as we look at improvements in our program. I would rather not get into the details of Texas A&M given that they have been referred to the Inspector General to assess whether civil or criminal penalties may——

Mr. STUPAK. I am not here to dump on A&M but I am just trying to say, without any kind of surprise inspection system, how are you going to know? I mean, you said documentation. How do you know if the documentation is valid? I mean, this Sunshine Project went through a Freedom of Information, went to the State agencies and found the information you should have been looking for and you were just there. So, I mean, if Sunshine can do it, why cannot you who are responsible for inspections figure out a way to double check, to truly audit, to be truly independent what we are all doing.

Dr. WEYANT. With each one of these events, we learn and we look to make improvements. And from our experience with Texas A&M and other institutions, there are additional documents, employee health records and such, that we will be looking at.

Mr. STUPAK. OK.

Dr. WEYANT. We will be looking to expand the pool of people that we interview and we look for, again——

Mr. STUPAK. Let me go to Mr. Burgess to see if he has anything further. We have got 5 minutes before we have to run down for two votes. We should be able to get right back and we can——

Mr. BURGESS. I know they will hold the votes for you, Mr. Chairman, so we will take the 5 minutes.

Mr. STUPAK. Sure.

Mr. BURGESS. Can I just ask a question for really anyone on the CDC side? If we find a problem, as was encountered at Texas A&M, should we not encourage a system that would promote voluntary reporting? You've got an issue, confess your sin, work on correcting it rather than a system that truly punitive. Design the system more like NASA, more like what we see with the nuclear submarine program that has such a proactive safety record.

Dr. BESSER. I think that is a very creative idea and something we need to explore. We do not want to have a system in place that actually leads to less transparency in reporting because of fear of penalties. We want a system where laboratories can learn from each other to prevent these from happening in the future.

Mr. BURGESS. Dr. Auchincloss, if I could ask you just in regard to NIH and funding for the NIH. Of course, you know this committee went through a rather lengthy and involved reauthorization process that culminated last year in December and finally just sent it to—work and we got a bill passed that reauthorized the NIH for the next 5 years, funding at about $30 billion a year to increase by 5 percent a year. We took a lot of grief for only increasing your budget by 5 percent every year and yet this year the House passed labor NIH's budget is about a 2.3 percent increase, if my arithmetic is correct. Is that your understanding as well?

Dr. AUCHINCLOSS. That is my understanding.

Mr. BURGESS. So why have you all not been more outspoken about not receiving your full authorized funding increase at NIH? Clearly, we are at a time in our Nation's history where if anyone needs a funding, you guys need the funding. We authorized a 5 percent increase. Again, we were criticized for it not being a 7 or 9 or 10 percent increase and we only managed to come up with 2.3 this year.

Dr. AUCHINCLOSS. We have research agendas for extreme drug-resistant tuberculosis, further work on influenza, such where we could spend the money.

Mr. BURGESS. Well, no question you can spend the money but really it is a question of planning too. How can you obligate or ask a young scientist to obligate their life to you when you are not sure that your funding stream is going to be steady? That was the whole purpose in reauthorizing the NIH budget last year. That is why we went through that long laborious process. I would just ask the NIH to help us make certain that your funding requirements receive no less the attention than every other thing that we deal with on this committee, whether it be the FDA regulation of tobacco or the lyrics of rap songs. Your work is every bit as important as that work and I want to hear from you. When we are not doing our job at the funding level, goodness knows, I heard from everyone last year, where were all your groups this year? Where was the NIH when your funding was cut by half, by over 50 percent, your funding increase was cut by over 50 percent, where was the involvement of the NIH?

Dr. AUCHINCLOSS. I got your point, Congressman, I do.

Mr. BURGESS. Very well. And you'll deliver that to Dr. Zerning? Thank you.

Mr. STUPAK. Less construction, more research. With that said, we will be at recess for about 10 minutes. We have two votes. This panel is dismissed. Thank you.

[Recess.]

Mr. STUPAK. Witness to come forward. That is Dr. Ed Davis, president of Texas A&M University. Dr. Davis, it is the policy of this subcommittee to take all testimony under oath. Please be advised witnesses have a right under the rules of the House to have counsel present and to be represented by counsel at this time. Do you have counsel with you, sir?

Mr. DAVIS. No.

Mr. STUPAK. OK. Witness indicates no. So then I would ask you to please rise, raise your right hand.

[Witness sworn.]

Mr. STUPAK. Thank you, sir. Let the record reflect that the witness has replied in the affirmative. He is now under oath. Dr. Davis, you'll have 5 minutes for an opening statement. You may submit a longer statement for the record if you wish. Dr. Davis, we'd like to have your opening statement please, sir.

STATEMENT OF ED DAVIS, INTERIM PRESIDENT, TEXAS A&M UNIVERSITY

Mr. DAVIS. Mr. Chairman and Ranking Member Barton, subcommittee members, my name is Ed Davis. I am president of Texas A&M University. As a brief point of personal privilege, I would like to acknowledge Mr. Barton's long service to the State of Texas, his district and to his alma mater, Texas A&M, as well as Mr. Chet Edwards, who accompanied me this morning here, who is our 17th Congressional District Congressman.

You might legitimately ask why the president of Texas A&M is here. I am not a microbiologist. I am not a doctor. I am not even a lawyer. But the answer is really pretty simple. Texas A&M has a proud heritage of scientific research. In fact, our 131st birthday is today and we have had a long history of providing service to our country. More importantly, however, is we have a history of being an honest, high-integrity and forthright institution in doing everything that is right.

I am here today as president to make four important points for the record. Number 1, we made a mistake. We failed to report an exposure to a select agent, *Brucella*, in a timely manner. The details of the incident are contained in my written testimony and I am pleased to give any additional details that you may wish. I am satisfied through our internal review that this was due to human error. It was compounded by a failure to have adequate protocols and redundant controls in place to ensure it could not happen. Number 2, we take this issue very seriously. I, as president, have become personally involved in this situation. I have devoted time and resources to assess what happened, to analyze appropriate corrective steps, and to move to implementation to return our program to doing the scientific work, the very important scientific work that benefits the public health system and the security of our country. Number 3, we are taking corrective actions to fix the problem. We want to rescue our research, revise the select agent registration with the CDC as our regulatory partner, hire and properly organize the best talent to lead our safety, security and compliance activity and re-establish the trust with the CDC, with you and with our research funding partners.

Finally, Mr. Chairman and members, we intend as a learning outcome of this episode, to develop in conjunction with you and the CDC a model program for select agent research and compliance to be in place across the country. In summary, we are committed to getting it right. We will use CDC's comprehensive review that has been provided as our road map to compliance and we will move forward from there. But we will leave nothing undone in moving our program to one of a model of documented excellence. This research is important, as I said, to our country's public health system and to our national security.

I think from the hearing today I have observed three protocols and partnerships that make sense and I think the hearing has been valuable for that. One is that we need to have good science. That is our job in conjunction with our funding partners. We need to have absolute compliance. That is our job with our regulator, the CDC. And we need regulatory oversight and coordination, which is the task of the hearing of this committee today. I think it provides value. We appreciate the opportunity to be here. I am here to answer any questions or provide further details. Mr. Chairman.

[The prepared statement of Mr. Davis follows:]

TESTIMONY OF EDDIE J. DAVIS

Mr. Chairman, Ranking Member Barton and members of the subcommittee, my name is Eddie Joe Davis, interim president of Texas A&M University at College Station. I have held this position since December 2006. The College Station campus is the largest of the 10 campuses that fall within the Texas A&M University System. I am appearing here today at the Subcommittee's request.

Texas A&M's College Station campus is home to approximately 38,000 undergraduate students at 10 colleges and approximately 7,000 graduate students. The University takes great pride in its reputation as a top tier research institution. I am here today to provide testimony regarding our select agent research laboratories. As you may be aware, these laboratories have recently been the subject of investigation by the Centers for Disease Control & Prevention or "CDC" and, as of June of this year, our select agent research work has been suspended pursuant to CDC's orders.

My comments today will first focus on some background information regarding the University's research program, internal compliance program and the select agent labs. I will then move on to the recent matters leading to the CDC's suspension of the University's select agent research and our commitment to run a model program to which others compare themselves. Finally, I will provide observations regarding the application of recent Federal regulations governing the possession and use of select agents in the laboratories that have emerged over the past few years.

I want to make it absolutely clear that Texas A&M University is, first and foremost, fully committed to both the safety and protection of our employees, students and community, and to following the guidelines and rules on safely and securely operating our laboratories that handle select biological agents and toxins. Only then, will we seek inspection and approval from the CDC to resume the research in these labs.

TEXAS A&M SELECT AGENT RESEARCH AND COMPLIANCE

Organizational Structure. The University's research organization falls under the Division of Research and Graduate Studies which carries out its mission through several internal units and a variety of external units and centers that are focused on important new fields of scientific inquiry. The work of the Division's units and centers spans the full range of scholarly endeavors and disciplines, securing Texas A&M University's place among the world's leading research institutions.

The Office of Research Compliance, which is a key unit of the University's Division of Research and Graduate Studies, is responsible for providing training and support to faculty, students and staff in regulatory requirements for scientific research. Through key committees and related programs and activities, the Office of Research Compliance develops, implements and oversees compliance with university policies and any applicable research requirements or regulations related to the following areas, among others:

- Research involving humans;
- Research involving animals; and
- Research involving hazardous materials, select agents or recombinant DNA.

Research projects involving infectious/biohazardous agents are subject to approval by the University's Institutional Biosafety Committee or "IBC." The IBC serves as the University's primary interface between the research institution, the Biological Safety Officer (BSO), and principal investigators (PIs) concerning lab review, security, safety, emergency plans, and other activities. In addition to the BSO, the University has also designated a responsible official or "RO" as required by the March 2005 Federal regulations promulgated by the Department of Health & Human Services for select agents and toxins. The RO is the University's designated individual who has the authority and control to ensure compliance with the regulations governing our select agent labs.

We presently employ an RO and a BSO, but in an effort to assure full compliance and seamless communications, we will combine these responsibilities into a single person who will report directly to high-level University management. At present, we have an on-going nation-wide search for a new RO/BSO and we expect to have this position filled by the end of the month. With the promulgation of the select agents and toxins rule, the roles of the RO and BSO have evolved and taken on additional responsibilities, which require unique skill sets and experience.

Select Agent Research Laboratories. Texas A&M University has a long history of applied and basic research involving Shiga toxin-producing E. coli, Brucella and Coxiella species with the goal of advancing the understanding of mechanisms of infection and disease, gene function, and vaccine development. The research efforts of our investigators have resulted in a better understanding of mechanisms of infection, which have yielded significant and relevant results with respect to immunogens for vaccine development, detection of the infectious agent and modes of delivery for achieving the highest probability for success in immunization against disease organisms. The collective contributions and over-arching theme of our research with Shiga toxin-producing E. coli, Brucella and Coxiella bacteria are in understanding host-pathogen interactions as the basis for prevention of disease. While these are zoonotic agents (i.e., agents that are transferable from animals to humans) and prevalent in the surrounding environment, most of the research focuses on diseases in animals and the economic impact of the resulting animal losses, as well as development of better human and animal vaccines. The recognition of the bioweapons potential of these particular agents has only served to make the ongoing research at Texas A&M more relevant and important. The four BSL–3 research laboratories at the University that are registered with the CDC as handling select agents are led by principal investigators Dr. Garry Adams, Dr. Thomas Ficht, Dr. Jim Samuel and Dr. Vernon Tesch.

Dr. Adams is a Professor and Associate Dean for Research and Graduate Studies in the College of Veterinary Medicine. Dr. Adams' research involves studies of the genetic basis of natural disease resistance, molecular pathogenesis of intracellular bacterial pathogens, and the development of vaccines and diagnostic tests against zoonotic diseases. For almost two decades, he has been actively involved in improving the scientific basis of the two largest animal health regulatory issues in the U.S.—brucellosis and tuberculosis. Recently, he has been very active in developing and implementing biodefense and emerging diseases research initiatives.

Dr. Ficht is a professor in the Department of Veterinary Pathobiology at the University's College of Veterinary Medicine. Dr. Ficht's research involves Brucella, an animal pathogen, which invades or persists in the phagosomal compartment of an animal's eucaryotic cells including professional phagocytes. His research explores host-agent interaction between monocyte-derived macrophages and Brucella with the aim of identifying the bacterial factors that subvert intracellular killing and the host factors responsible for protecting the host from infection.

Both Dr. Samuel and Dr. Tesch are Associate Professors in the Department of Microbial and Molecular Pathogenesis in the College of Medicine at the Texas A&M University System Health Science Center. Dr. Samuel's research involves identifying recombinant vaccine strategies to elicit protective immunity to the obligate intracellular bacterial pathogen, Coxiella burnetii, the etiologic agent of Q fever and a biothreat agent. Dr. Tesch's research involves a family of bacterial toxins called Shiga toxins known to cause disease in humans. Shiga toxins are produced by Shigella dysenteriae and E. coli. These microorganisms have been in the news lately, as the ingestion of undercooked hamburgers or other foods contaminated with Shiga toxin-producing E. coli may lead to widespread outbreaks of bloody diarrhea. A fraction of patients, mostly children, go on to develop life-threatening complications involving acute renal failure and neurological abnormalities.

Texas A&M University has been conducting research involving the propagation of Brucella since the late 1970's and has performed research using BSL–3 facilities since the mid 1990's. Research in the other BSL–3 laboratories has similarly been on-going for some time. In addition to the four research laboratories, two BSL–3 diagnostic laboratories are operated by the Texas Veterinary Medical Diagnostic Lab (TVMDL) located at the College Station campus. From its inception, the TVMDL has occasionally received tissue or blood samples from animals which contain biological agents and toxins (e.g., rabies, e-coli, and Brucella) and, therefore, it must be equipped to handle these samples in a high containment laboratory.

CDC'S INVESTIGATION OF TEXAS A&M'S SELECT AGENT RESEARCH LABS

I now would like to turn our attention to the reported exposure of a University lab worker to the select agent Brucella and the resulting CDC investigation of the University's select agent labs. I will first address the details of the exposure and follow that up with comments regarding the CDC's investigations earlier this year.

2006 Brucella Exposure. In February 2006, a post-doctoral research associate in Dr. Thomas Ficht's lab was conducting an experiment involving brucellosis using a Madison Chamber. A "Madison Chamber" is an aerosol infection chamber that is used to infect test animals with various pathogens. The use of the chamber for this experiment was loaned to Dr. Ficht's research associate by another researcher at the University's Health and Science Center, who used the chamber for tuberculosis research. A Ph.D. research assistant involved in the tuberculosis research which uses the Madison chamber was present during the burcellosis experiment conducted by Dr. Ficht's research associate. The research assistant is proficient in the operation of the Madison Chamber from her use in research concerning tuberculosis. At the time of the experiment, she was present in Dr. Ficht's lab to observe the proper use of the chamber by the research associate who was working with Brucella. After the experiment had concluded and the test animals removed, she cleaned the chamber as she would if the pathogen had been tuberculosis.

About 2 months later, the research assistant notified Dr. Ficht that she was ill with flu-like symptoms and inquired as to whether or not anyone else was ill. On that same day, Dr. Ficht had all other lab employees who were present during the experiment in February tested and notified the BSO. Within the next two weeks, the research assistant was diagnosed with Brucellosis and, through blood testing, it was confirmed that no other employees had contracted it. The research assistant's positive test for Brucella was entered into the public health database by the Brazos County Health Department, which was automatically transmitted to the Texas Department of Health and CDC. The research assistant returned to work, was given follow up blood testing and has continued to be monitored pursuant to the institution's occupational health program.

In October 2006, the University received a request for public documents involving incident reports for risk group 2 and higher pathogens from Mr. Edward Hammond of the Sunshine Project, one of the witnesses at today's hearing. In November 2006, the University produced a document showing that there had been a single incident relating to brucellosis. The University continued to inquire internally as to whether there were any additional documents. In April 2007, additional documents were identified regarding the Brucella exposure. At that time, the University immediately notified CDC and provided the documents to Mr. Hammond.

CDC's 2007 Investigation. Following the notification to CDC, the University received a notice of suspension of select agent research in Dr. Ficht's lab. Inspectors from CDC then visited the University to follow-up on the notification of exposure and conducted an inspection of the University's four BSL–3 laboratories. A few weeks later, the University submitted information to CDC regarding elevated titers for Q fever—a term of measurement of antibodies in the blood—for three employees who worked in Dr. Jim Samuel's lab. Although it was not clear whether notification was required for these elevated titers, the University elected to report these levels to CDC out of an abundance of caution. While these elevated titers were cause for concern, none of the individuals became ill. Following this disclosure by the University, the CDC issued an order suspending all select agent research at the University. The University immediately complied.

On July 23, 2007, an 18-member team from the CDC conducted a comprehensive site review of the University's select agent research activities which ultimately led to the CDC's August 31st site visit report. Though the CDC's report acknowledged the efforts of the University in curing the deficiencies noted by the CDC inspectors, we acknowledge that several additional steps need to be accomplished in order to be re-certified for select agent research. Our No. 1 goal is to ensure that our laboratories are operated in a safe and secure manner, in compliance with all applicable laws and regulations.

We are using CDC's August 31st site report as our roadmap to full compliance. In fact, we have already begun to take corrective action to cure many of the deficiencies cited in the report and have engaged outside experts—some of who were recommended by the CDC—to assist in this process. This will continue full speed ahead. Only after we have satisfied ourselves in the areas of biosafety, security, training, recordkeeping and incident response, we will ask the CDC to allow us to re-start the laboratories. We desire to get back to the important business of vaccine research, with the CDC as our partner, as soon as possible.

MARCH 2005 CDC REGULATIONS COULD USE SOME CLARIFICATION

I would now like to turn our attention to the Select Agent and Toxins regulations that were promulgated in March 2005. These regulations are found at 42 C.F.R. § 73.1 et seq. and were developed pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. These Federal regulations pertain specifically to the possession, use and transfer of select agents and toxins and I will refer to them as the “SAT Regulations.”

Like many labs in the U.S. handling select agents and toxins, we have grappled with compliance with these regulations. Over the past two and one-half years since their promulgation, several areas have emerged which we believe need further clarification or improvement. I address a few of these areas below:

Definitions—perhaps the most challenging aspect of the SAT Regulations pertain to definitional interpretations of key terms. The possession, use and transfer of select agents and toxins in biomedical laboratories is a highly complex scientific endeavor. Added to that is the need to operate the laboratories in a safe and secure manner. Given these complexities, the application of definitional terms in the regulations can take on different meanings given different operating scenarios. Terms that are broadly defined can take on different meanings to different people, which can result in differential application and enforcement of the regulations. The following terms in the SAT Regulations have led to a good deal of confusion:

“Access’ to select agents or toxins. 42 C.F.R. § 73.10(a) restricts access to select agents and toxins to only those individuals that have been approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General. Whether someone has access or not depends on “if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.” 42 C.F.R. § 73.10(b) (emphasis added). While the former condition (has possession) is straightforward, it is the latter condition that creates the bulk of the confusion (has the ability to gain possession). For example, does someone who has not been pre-approved and observes an experiment in a select agent lab have the ability to gain possession of the select agent? Or, if the select agent or toxin is in an animal that is locked in cage within the lab, does that change the analysis? Presently, the definition of access to select agents or toxins is interpreted to be extremely broad. Some degree of reason needs to be applied to the rule in order to facilitate good laboratory practices and the advancement of scientific research. The effect of the broad application of the definition is that any person who enters a SAT lab could arguably have access to the select agent and, therefore, must be pre-approved.

“Routine cleaning, maintenance, repairs, or other activities not related to select agents or toxins” 42 C.F.R. § 73.11(d)(2) provides for certain exceptions to the rule requiring that individuals entering a SAT lab be pre-approved. The exception in (d)(2) specifies that an individual who conducts routine cleaning, maintenance, repairs, or other activities may gain access to the lab so long as (1) his or her activity is “not related to select agents or toxins” and (2) he or she is accompanied by an approved individual. The exception is often confused with the requirement set forth in ♦ 73.10(b) as described above. Furthermore, it is unclear what is meant by an activity that is “not related to select agents or toxins.” Does the maintenance or repair of a vent hood that is used for the handling of select agents or toxins fall within this exception? It could be argued that any activity within a select agent or toxin laboratory is “related” to the agent or toxin handled in that laboratory.

“Occupational exposure or release” of a selection agent or toxin. 42 C.F.R. § 73.19(b) specifies the notification requirements in the event of a release of a select agent or toxin. The trigger for the notification is based upon whether there is an “occupational exposure or release of a select agent or toxin outside the primary barriers of the biocontainment area.” The SAT Regulations do not define the terms “occupational exposure” or “release,” leaving both the regulator and the regulated without clear direction as to what is expected. In terms of select agents and toxins, there is little guidance as to what constitutes an occupational exposure (e.g., mode of the exposure or acceptable limits or levels?).

“Restricted experiments.” 42 C.F.R. § 73.13(a) establishes a requirement that an individual or entity may not conduct certain “restricted experiments” unless approved by the HHS Secretary. Subsection (b) sets forth two types of restricted experiments—experiments using recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents and experiments that involve the deliberate formation of recombinant DNA containing genes for the biosynthesis of select agents. While there are likely strong public policy reasons for restricting these types of experiments (based upon the ultimate end use) without express approval from HHS, these two types of restricted experiments are very broadly defined and may unintentionally limit legitimate experiments involving similar approaches but result in completely different outcomes (and end uses).

Authorization of Access to Select Agents and Toxins—another area of confusion involves the authorization of an individual's access to a select agent or toxin. 42 C.F.R. § 73.10(a) states that "[a]n individual or entity—may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or Administrator, following a security risk assessment Attorney General." The confusion arises as to whether the authorization of an individual is (a) as to a specific select agent, wherever that select agent might be handled, or (b) as to a specific select agent handled at a specific location. If the latter interpretation is correct, the authorization requirement becomes a bureaucratic paperwork mess. For example, a research scientist and his/her staff who work with Rickettsia prowasekii (a select agent) may, from time to time, visit the labs of or work with other research scientists who handle the same agent. Requiring that scientist and his/her staff who are already authorized to access this select agent at their home lab to obtain authorization anytime they visit another lab or location where the select agent is handled serves no purpose, nor does it achieve any public policy. The regulation should be clarified such that the authorization applies to the specific agent in question, not the specific agent and location. The focus of the authorization should be, first, on the individual (which is why there is a security risk assessment on the individual) and, second, on the handling of the select agent.

In closing, I want to express my appreciation to the CDC for providing a comprehensive review of the steps necessary to rebuild the compliance model for our select agent and toxin research program at Texas A&M. As I mentioned previously, we are using it as our road map to full compliance.

The University has made significant progress in implementing corrective actions that cure the deficiencies noted by CDC in its findings and has brought in outside experts, including several recommended to us by CDC, who have aided us greatly in the process. Our efforts will continue at full speed ahead until we have satisfied the CDC and ourselves. Our goal is for the University's select agent labs to be the model to which others compare themselves.

Mr. STUPAK. Thank you, Dr. Davis. We will begin questioning. We will see if Mr. Barton would like to start.

Mr. BARTON. Mr. Chairman, I am willing to go first but I am also willing to let the Chair exercise its prerogative to question first.

Mr. STUPAK. You are the graduate Texas A&M. Why do not you go first?

Mr. BARTON. All right. I will be happy to. I think in full disclosure, Mr. Chairman, I need to say, not only did I attend Texas A&M, my father attended Texas A&M, my three children attended Texas A&M, numerous aunts, uncles, nephews, nieces and cousins have attended Texas A&M. If you added up all the relatives who have had the privilege to go to that institution, it would be in the neighborhood of 30. So I am a biased questioner in favor of Texas A&M. But having said that, as a Member of Congress and this subcommittee and the past chairman, I am absolutely committed to getting to the bottom of what went wrong and making sure that it does not happen again. Mr. Davis, as acting president of Texas A&M, when were you first made aware of the *Brucella* exposure and how was it reported to you?

Mr. DAVIS. In April 2007, Congressman Barton and I was notified that we had discovered that there was an error and a failure to report within the timeframe required by the select agent regulations. This did come about through a request from the Sunshine Project for us to produce documents related to our select agent program. And as we did review those documents and discovered that this incident was not reported, as soon as we discovered it, we did report the incident and at the same time, provided that information to the Sunshine Project. The reason the incident was not reported is fairly and lengthy and detailed but I think it is important that I give you some summary of what happened. A laboratory worker was actually an authorized person in a lab observing the use of an aerosol piece of equipment, which she was using for tuberculosis research. This chamber was then used in a *Brucella*s experiment in a different laboratory. After she had completed that work, the other researcher, the person that was actually providing the machine, cleaned the machine unbeknownst to the laboratory technician that was conducting the research. As a result, her exposure to the Madison Chamber, we believe is where the infection came about. A few weeks later she became ill with flu-like symptoms. She went to her doctor. She was diagnosed with the flu and, ultimately, through a couple of trips back to an infectious disease doctor, found that she had, indeed, been exposed to *Brucella*s. At that time, she went back to the principle investigator, informed him of this. He immediately informed our biological safety officer, where the failure to report to the CDC occurred. He did have the rest of his lab workers tested. No one else revealed any indication of *Brucella*s or brucellosis and the individual that was infected was treated and has been cleared and has been routinely tested since that time, with no adverse effects.

Mr. BARTON. The individual that was infected was infected in doing a procedure which she did voluntarily and was not instructed to do so against protocol, is that correct?

Mr. DAVIS. That is correct.

Mr. BARTON. But in spite of that, this employee is currently cured and, so far as you know, has no complaint against the university, is that correct?

Mr. DAVIS. That is correct.

Mr. BARTON. OK. Now you mentioned that there was an exposure incident of *Brucella*, we have talked about that. It is my understanding that there was also a Q fever exposure that went unreported. Can you comment on that?

Mr. DAVIS. I think it is helpful to clarify that. After our *Brucella* report and a visit by the CDC, after the CDC had come in in April to review this incident with us, after their departure, we were reviewing documents and discovered that we had elevated titers in three employees who were actually involved in Q fever research. We do titer testing, obviously, to determine from a public health standpoint, if anyone has had exposure, it allows us to understand if they should be referred to a physician for possible treatment. In these cases, it was not clear that we were required to report the titers. We did it out of an absolute abundance of caution because we had just not reported *Brucella*s.

Mr. BARTON. This was after the *Brucella*.

Mr. DAVIS. This was after the *Brucella*s incident and after their visit. We felt it was important that we absolutely reveal anything that was of any concern. Unfortunately, after we did report the Q fever incident, shortly after that, the CDC suspended our select agent research.

Mr. BARTON. Now currently, is the Texas A&M University system fully cooperating with the CDC in their investigation or re-examination of the facilities and procedures at Texas A&M?

Mr. DAVIS. Yes, we are. We have, of course, received their August 31 report. We have had a team of individuals, including outside experts, helping us with the response to that report, as well as the reconstruction of a total re-registration of our select agent program.

Mr. BARTON. And so long as you are the acting president of Texas A&M, are you committed to doing everything within your power to make sure that A&M fully complies with the CDC directives and cooperates in every way to ensure the safety of these agents if this type of research is allowed to be commenced again?

Mr. DAVIS. Mr. Barton, we are absolutely committed to the research, to the safety, to the compliance of this research. Absolutely.

Mr. BARTON. Mr. Chairman, before I yield back, I want to recognize, I think, the chairman of the board of regents at the Texas A&M University system is in the audience, Mr. John White, and I think that shows the seriousness with which the university takes this matter. With that I yield back, Mr. Chairman.

Mr. STUPAK. Well, thank you, Mr. Barton. All the people went to Texas A&M in your family, I thought you would end up by saying they named a lab after you.

Mr. BARTON. Well, there is an Olin E. “Tiger” Teague Research Center at Texas A&M, who was my predecessor and who Congressman Edwards worked for as a district aid. So there is Aggie sixth district congressman facility on campus but it is not named after Joe Barton.

Mr. STUPAK. You’ll have to do a Chet Edwards, right? Dr. Davis, this is a level 3 lab at Texas A&M, right?

Mr. DAVIS. Yes, sir.

Mr. STUPAK. OK. Are you in the process of expanding that lab at all?

Mr. DAVIS. We are not. In our revised registration documents, Mr. Chairman, we are actually recommending to the CDC that we re-activate two of our laboratories. The two other laboratories, or four in total, we have some physical corrections to make to that but we are not seeking immediate re-registration of those other two. Not until we have them fully in compliance will we ask the registration to include them

Mr. STUPAK. Were you here when the last panel testified?

Mr. DAVIS. I was.

Mr. STUPAK. OK. I asked about unannounced inspections. Do you think CDC should do unannounced inspections?

Mr. DAVIS. I think we should have a program that can endure any kind of inspection, Mr. Chairman, announced or unannounced. I also believe, and this goes back to another question I believe you asked and it is related to Mr. Barton’s question, the idea of no fault reporting, it seems to us, is a very valid concept and should be pursued. We should be encouraged to report any kind of occupational exposure or loss. And there needs to be greater definition of those things.

Mr. STUPAK. Congressman Edwards explained to me a couple times that the person who is in charge of safety of your labs there has been terminated from employment and you are going about correcting it. Any suggestions on how we do this? I heard a lot from the CDC saying, well, we got documentations, we will be questioning this and looking at this. And in the Texas A&M case, the people who were in charge of certain things within the lab had all that documentation. Maybe not to the level it was supposed to be but they had that documentation and CDC passes you through and then because of the Sunshine Project, we find there were greater concerns. They come back in with their team and they find serious violations. Any suggestions on how we can make sure CDC, or whoever is going to do it, do these inspections for independent verification so we do not have this situation again? As the president of Texas A&M, I am sure you got the report from CDC saying everything is fine and then boom, we find things are not so good.

Mr. DAVIS. Certainly it is something that I would not be expecting on a daily basis to be involved in but I am involved in it now and I do have some thought about how we go forward. Frankly, I think this hearing is a positive view of what needs to be done. You've revealed some issues, some lapses in the overall integration of the select agent program and the biological research program. I think it is more complex than just inspections. I think what we have to have, it is very interesting as I analyzed the exit interview from the CDC, this was in an oral exit interview, one of the things that became very clear to me was that there was a gap between the understanding at the research compliance office and what was going on in the labs. And part of that misunderstanding was the fact, if you do not document it, you have not done it. It is a bit like Sarbanes-Oxley issues. So what we actually did is employed an expert in the scientific compliance area, Dr. Claudia Mickelson, from MIT with an expert in accounting in Sarbanes-Oxley compliance because we thought we needed to be much better at transaction process documentation. You need to know when people are entering the lab. You need to know who is on the registration. You need to be sure those things are protected. It is a very complex environment which this is all about. But let me give you one other example of why it is so complex. Our re-registration document now is 900 pages, going toward 1,000. We are not finished. That is for four labs that would fit inside this hearing room. There is a huge amount of work that has to be done on not just writing the regulations and implementing them but having the time to make those regulations work together so that everybody understands what the expectations are and the expectation has to be safety, security and good science.

Mr. STUPAK. I understand that and also you have to have the people in there who are trained to do it. Like your biosafety person who was the biosafety officer at A&M. Had no training in biosafety but was an industrial hygienist by education, experienced and he was asked to take on these extra duties. Who would have made that decision, the head of the lab, your safety officer?

Mr. DAVIS. Of the person that was there before?

Mr. STUPAK. Right, who was assigned these extra duties, who wasn't qualified to do it.

Mr. DAVIS. Well, I do not know who made that decision. I wasn't there at the time. I will tell you this, we are currently advertising and seeking a new biological safety officer that will also be our responsible official in interacting with the CDC. We are looking for a much greater level of expertise. That is, we want someone who is an accomplished scientist with experience in the area of biological compliance. And we have two good candidates and we hope to have that filled within just a very short period of time.

Mr. STUPAK. Do you think the communities have a right to know what is going on at these labs?

Mr. DAVIS. Absolutely.

Mr. STUPAK. There was some reluctance from the last panel to let them know what agents or what we are doing at these labs but that can be part of the checks and balance, can it not?

Mr. DAVIS. It does. One of the recommendations of the GAO that I heard this morning I think is very sound is that we need to work with the community health providers to be sure they know what we are working on in the laboratories, so if there is an exposure, accidental or otherwise, they recognize the symptoms if it comes from someone who is working in one of these labs.

Mr. STUPAK. It is Mr. Green's. I will turn to him for questions just in a second. Let me ask you this and hopefully we can all learn from the Texas A&M situation. You are telling me your re-license is up to almost 1,000 pages now. I am sure as you talk with other university presidents and others who have labs on their academic facilities, you must have heard from others saying, boy, they are putting you guys through a wringer. We got to tighten up ourselves. Is that pretty common? I am not asking you to blow the whistle on anybody but I am just saying, it seems like this has been pretty shoddy the way we have been doing it throughout this country, even with the proliferation. We really need to look at this in more detail. Not that we are trying to tie up research but, at the same time, it just seems like this has been sort of an area we never paid much attention to until we really—and unfortunately, your sort of institution that sort of got looked at closer.

Mr. DAVIS. This is not the type of role model we would like to be, Mr. Chairman. However, I think our episode and the revelations of this hearing will probably cause others to awaken to the need to be very vigilant about these issues and to really focus on both the regulations and their interactions with the regulating agency.

Mr. STUPAK. Well, my time is up and as you can see, Texas A&M has a lot of support on this committee. I am the only one here not representing Texas A&M. So with that, let me turn it to Mr. Green for questions or do you want to go, Mr. Burgess? Go ahead, Mr. Green, you would have been next anyway.

Mr. GREEN. Dr. Davis, thank you for being here and I can imagine under uncomfortable circumstances because those of us who are familiar with Texas A&M and high institutions are not found when something bad happens. But the good thing about it is when something bad happens you also want to fix it and that is what I am proud of that we are problem solvers. I wish I could tell you I always voted right but if I find out it was wrong, then I will fix it somehow. And I hope you know your testimony before us today providing us with the lessons it learned, which can make sure that our regulatory gaps are filled. And my last series of questions from CDC, I mentioned the need for rigorous training of lab workers and the CDC mentioned that labs should have a biosafety plan, emergency response plan, a security plan among others. And its investigations in the incidents at A&M, GAO noted that the infected researcher had a wealth of experience in BSL–2 labs in particularly tuberculosis. She was then called in to a BSL–3 lab to work on *Brucella* despite not receiving training on that specific agent. Did any biosafety plan speak to the specific protocols when alternating between BSL–2 and BSL–3 labs?

Mr. DAVIS. Yes, Congressman Green, it did. Unfortunately, a modest change in that and that is the worker actually volunteered to participate in the experiment because she was familiar with the Madison Chamber, which was used in tuberculosis experimentation and was being loaned in the lab that was doing *Brucella*s experiments. So that is not an excuse, it is simply a statement that it is quite different then that she was urged to do it or asked to do it. It was a voluntary activity.

Mr. GREEN. The GAO office spoke to laboratory experts who highlight inherent safety risk when researchers switch from BSL–2 to BSL–3. And the GAO noted that the procedures, protocols are different among labs and the researchers really need to make sure that their safety protocols become part of their routine. From the university research program perspective, is this a point made clear to select agent programs either through the CDC or other safety guidelines? Do you know if that was made plain to A&M?

Mr. DAVIS. Well, clearly from the interactions we have had with the CDC and the GAO, we are very engaged in improving and upgrading our safety plans, our training plans. Actually, during the time that our laboratories are not in operation, we are taking advantage of that time, in addition to getting our documentation completed. We are also having training sessions with the individuals that are assigned to the laboratories, including specific training on the select agents in which they are working. So indeed, we are taking advantage of this time to improve our safety, security and capacity to do the research.

Mr. GREEN. When the CDC visited A&M in February 2006, days after the unknown exposure occurred, was there any mention from the CDC about the need to implement training protocols for researchers specific to the agents they were handling?

Mr. DAVIS. I cannot answer that, Mr. Green. I do not know what was contained in the report in their February 2006 visit. I was not in place at the time.

Mr. GREEN. OK. Well, I guess from the testimony from our earlier panels and seems like there is enormous lack of clarity in the system and when it comes to authorities and the responsibilities and protocols on the part of the Federal agency and also individual research institutions and given the nature of these agents, I think the questions need to be crystal clear to both the agency but also to our institutions. And I look forward to working with you, of course, the CDC, NIH and other schools to see if we can get that so we do not have a repeat of what happened at Texas A&M and maybe happen somewhere else that we do not know about as we sit here today. Thank you, Mr. Chairman.

Mr. DAVIS. One of the positive outcomes of this is we do have an opportunity to get better, all of us do and that is what we intend to do.

Mr. GREEN. Thank you.

Mr. STUPAK. Thank you, Mr. Green. Mr. Burgess, questions please.

Mr. BURGESS. Thank you, Mr. Chairman, Dr. Davis. Thank you for being here with us and ensure your commitment to making sure we get it better and my responsibility being on this committee is being sure that we give you the tools that you need, give your researchers the tools that they need so they are protected and in turn they protect us. Let me just ask you briefly, the individual that was involved with the brucellosis incident, was that an experienced lab worker, was that a student, what was that person's role in the lab?

Mr. DAVIS. She was a research associate. She was a Ph.D. scientist. She was experienced in laboratory activities and safety protocols.

Mr. BURGESS. Did the extent that you are able to disclose it with all of the Federal regulations regarding HIPAA, can you tell us the condition of that individual today, what their health status is?

Mr. DAVIS. Her health is fine and we continue to monitor her for any reoccurrence.

Mr. BURGESS. OK. So she was treated and responded to—OK. Well, that is good news. Let me ask you this because I mean, A&M, most people may not know this but you are the only school of veterinary medicine in our State and probably in the region. The Brucellosis is not really a new infective agent. Brucellosis has been around for a long time. Has your university been involved with the study or work of Brucellosis in the past?

Mr. DAVIS. Yes, sir, for quite a long time. Actually before we knew what a select agent was, we were working on Brucellosis research. My guess is probably as early as the early part of the 20th century because Bangs Disease or Brucellosis in cattle has been a major issue and problem in the State of Texas. So Texas A&M has actually lead in that. We have had laboratories in place, the BSL–3 type laboratories, since the middle '80's, prior to the select agent program, implementation working on Brucellosis research.

Mr. BURGESS. So even going back into the early part of last century, even though you were not able to or your predecessors were not able to intuit, that this agent would be a select agent in the 21st century, you had ongoing procedures and protocols to protect from contamination and protect your laboratory workers?

Mr. DAVIS. Yes, sir, we did. This research was primarily in animal-borne diseases and zoonotic diseases related to those pathogens.

Mr. BURGESS. Well, before we were called for this hearing today, have you expressed concerns to the CDC about the ambiguities regarding the CDC's handling of the select agents, the rules for handling select agents? Do you feel like those have been delivered to you a timely fashion with the appropriate clarity to allow your researchers and your lab personnel to make the correct choices and assignments?

Mr. DAVIS. As we mentioned a while ago, I think there are some areas that still remain unresolved, such as the definition of an occupational exposure, so that there is clarity and there is also a promotion of open reporting of incidents. There are probably a few other areas that are related to the security issues with select agents where you have to have the Department of Justice approval for individuals participating in particular laboratories. Currently, the approval is related directly to the laboratory that the individual might work in. So if you have a visiting faculty member going to another lab using the same type of pathogen, they are not eligible unless they are cleared again. And we think there are some improvements there but these are modest and we are certainly working with the CDC to try to find ways to reach agreement on all of those.

Mr. BURGESS. And do you collaborate with any labs that are from outside the country? I will respond going forward and making sure that we write the correct protocols or will write the correct legislation that allows you to write the correct protocols for the protection of your community and protection of your workers. I mentioned at the previous panel that was up here the concept of rather than having a punitive system, to have a no fault system similar to NASA, similar to commercial aviation, similar to, again referencing the nuclear submarine program in this country that has a remarkable safety record. A culture of not tolerating any security lapses or any safety lapses but at the same time, rather than coming down with extremely punitive measures, suspending a license or suspending your ability to do the work you are trying to do, to work in a collaborative fashion to learn from the mistake and go on and make sure we are going forward, that we have the correct procedures in place. Is that something that you are exploring internally in the university right now?

Mr. DAVIS. We are very much in favor of that and would love to see that and implement it.

Mr. BURGESS. But are you working toward that specific goal?

Mr. DAVIS. Our position is we will report anything that we suspect falls under the rules as an occupational exposure, although we are currently still trying to get absolute definition of what that is.

Mr. BURGESS. Again, I thank you for your generous contribution of time today for this committee. I think you have been very helpful with providing insight and Mr. Chairman, how we can craft the appropriate legislation that will not stymie this research but, ultimately, we all have the same goal in mind and that is protecting our country. So with that, I will yield back.

Mr. STUPAK. Mr. Barton and I were talking about my series of votes when I walked back here, some things we should or could be doing. I am a little confused here, maybe you can help me out. This Sunshine Project, right, that reported the stuff. Sunshine Project? Sunshine Project. They foiled the information from Texas A&M, right, and received the information from Texas A&M?

Mr. DAVIS. Well, in our case it is open records but the same——

Mr. STUPAK. But they got your records?

Mr. DAVIS. Yes.

Mr. STUPAK. Then why did not the CDC notice those problems when they were there with their inspection, when they said everything was fine?

Mr. DAVIS. I cannot answer that, Mr. Chairman.

Mr. STUPAK. And they would have access to it, right?

Mr. DAVIS. Absolutely. I will tell you, however, that when we received the request from the Sunshine Project——

Mr. STUPAK. OK.

Mr. DAVIS. We do not have a system that accumulates everything that is going on in laboratories without going through keyword search.

Mr. STUPAK. Sure.

Mr. DAVIS. And so it did take us some time to actually locate and dig out the documents which gave us the alert that this exposure occurred.

Mr. STUPAK. Right.

Mr. DAVIS. And so I think it is fair to say that the CDC probably did not do that same level of inquiry and that is why we discovered it and passed the information onto both them and the project.

Mr. STUPAK. But in order to get it into Texas A&M archives or your stuff.

Mr. DAVIS. Electronic.

Mr. STUPAK. Yes. Someone reported it electronically?

Mr. DAVIS. Yes, sir.

Mr. STUPAK. And then when the Sunshine Project put forth, did the keyword search, that is when it popped up.

Mr. DAVIS. We did the keyword search based on their request.

Mr. STUPAK. And you actually provided them with the information.

Mr. DAVIS. That is correct.

Mr. STUPAK. So CDC should have at least, knowing its electronic, could have done an electronic search or then but where would your lab person be?

Mr. DAVIS. They could have asked us to do the electronic search.

Mr. STUPAK. Sure. They could have asked you. Even if—inspection team, they just could ask you to do a key search and you would have.

Mr. DAVIS. Right.

Mr. STUPAK. But this report then, would not the lab director know? Your lab director know about this?

Mr. DAVIS. He did and as soon as he detected it, it was reported to the biological safety officer.

Mr. STUPAK. Right.

Mr. DAVIS. Which reported through——

Mr. STUPAK. This is the public health.

Mr. DAVIS. Yes.

Mr. STUPAK. OK. That had the right training.

Mr. DAVIS. That is correct.

Mr. STUPAK. OK.

Mr. DAVIS. I know it sounds Byzantine but, indeed, it was and that is the reason we failed to report it.

Mr. STUPAK. OK. Did the Government Accountability Office come down and do an inspection at Texas A&M?

Mr. DAVIS. They came and visited with individuals at our university. I do not know if I would characterize it as a review or inspection.

Mr. STUPAK. OK. Was that after this incident was made public about the Sunshine Project, do you know?

Mr. DAVIS. They were here this August, which was after.

Mr. STUPAK. It was after.

Mr. DAVIS. And then they were here in November 2006, which would have been, I guess, also after the incident occurred but not after it was reported. It was reported actually in April of 2007.

Mr. STUPAK. I know GAO's been, in all fairness, Chris Shays had a position in a different committee, Homeland Security, and started this whole GAO and that was in 2005. And I thought it was a good idea, so we picked up on it and so I know it has been going on for some time, that is why I asked that question. My question base prompt any other questions, Mr. Barton, Mr. Burgess, Mr. Green? If not, Dr. Davis, thank you and we will call for our next panel, our last panel of the day.

Mr. DAVIS. Thank you.

Mr. STUPAK. The last panel is Dr. Gigi Kwik Gronvall, senior associate and assistant professor of medicine at the University of Pittsburgh Medical Center, Center for Biosecurity. Dr. Alan Pearson, who is the director of the Biological and Chemical Weapons Control Program at the Center for Arms Control and Non-Proliferation. And Mr. Edward Hammond of the Sunshine Project. If you would come forward please.

It is the policy of the subcommittee to take all testimony under oath. Please be advised witnesses have the right under rules of House to be advised by counsel during your testimony. Do any you wished to be represented by counsel? Everyone shook their head no so I will take it for a no. Then I am going to ask you to please rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect the witnesses have replied in the affirmative. You are now under oath. We have 5-minute opening statements. You can submit longer ones for the record. We ask Dr. Gronvall, do you want to go first here?

STATEMENT OF GIGI KWIK GRONVALL, SENIOR ASSOCIATE, ASSISTANT PROFESSOR OF MEDICINE, CENTER FOR BIOSECURITY, UNIVERSITY OF PITTSBURGH MEDICAL CENTER

Ms. GRONVALL. Thank you, Mr. Chairman, distinguished members of the committee. I have submitted written testimony but I will summarize those in my oral remarks. First, I would like to make it clear that it is urgent that the Nation finds ways to protect itself against large scale epidemics. In fact, it was the recognition that there needed to be research to form those methods of protection, the medicines and vaccines that are needed that led to the expansion of the high-containment laboratories in the first place. Without these high-containment laboratories, critical research cannot be performed. However, these labs need to be safe otherwise they cannot operate. And so I will highlight several actions which could be taken to help ensure that these new labs are both safe and productive in the future.

The first action that could be taken is to increase biosafety training. The way that people learn biosafety and high containment, the way that I learned biosafety, was to apprentice to a more senior, knowledgeable person. However, with the expansion of laboratories, there may not be enough senior knowledgeable people to go around. And so one solution is to standardize the training and require certification for high-containment work.

You can also increase the number of biosafety officers who are credentialed for high-containment work, so they can provide training and they can provide guidance as research is being conducted.

The second action which could be taken is to develop a reporting system so that all mistakes, near misses are captured, learned from, and the results disseminated across high-containment laboratories. One model that may be useful is that used for aviation safety reporting. It was set up because it was found that most aviation incidents and accidents had common root causes. But because these incidents were not being reported, they were not being learned from and so the new accidents were not being prevented. So that is one potential model where people are encouraged to report.

The third action which could be taken is to share lessons and operational experience across the high-containment laboratories. In particular, it should be easier for a more senior, knowledgeable person to conduct training in multiple high-containment laboratories.

The fourth action which could be taken is to make public engagement a priority. Public engagement is essential to the success of these laboratories. The community has a right to know that the people who are working in these high-containment laboratories are well trained, that if there is an accident, that it is being dealt with appropriately. Some labs have done a better job of this than others. And so the successes of some of these labs should be taken as lessons learned and disseminated across the high-containment laboratories and emulated.

So finally I just want to point out that this is not a domestic issue. This is a global issue and these labs are expanding all over the world because these countries recognize that these are important for not only work on SARS and avian influenza and diseases like this, but that it could be a major part of economic growth in the 21st century. Thank you.

[The prepared statement of Ms. Gronvall follows:]

TESTIMONY OF GIGI KWIK GRONVALL

Mr. Chairman, distinguished members of the committee:

Thank you for the opportunity to speak to you today. My name is Gigi Kwik Gronvall. I am a Senior Associate at the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) and an Assistant Professor at the University of Pittsburgh School of Medicine. The Center for Biosecurity is a nonprofit, multidisciplinary organization located in Baltimore that includes physicians, public health professionals, and biological and social scientists. I am a biological scientist, trained in laboratories at Johns Hopkins University and the United States Army Medical Research Institute for Infectious Diseases (USAMRIID). My colleagues and I at the Center for Biosecurity are committed to the development of policies and practices that help prevent bioterrorist attacks or destabilizing natural epidemics and, should prevention fail, that mitigate the destructive consequences of such events.

It is a privilege to come before you today to discuss the expansion of high-containment BSL–3 and –4 laboratories. Protecting the Nation against destabilizing large-scale epidemics, whether natural or man-made, is an urgent priority. The anthrax attacks in 2001, the SARS epidemic in 2003, and the current threat of avian influenza all are important reasons why we must conduct research to determine how microbes work and how to defeat them with medicines and vaccines. These new high-containment biological laboratories are needed to provide the safe, protective environment necessary to do this research. In high-containment laboratories, potential bioterrorism agents such as Ebola or Marburg, as well as emerging diseases such as SARS and avian influenza, can be safely studied and understood. The labs can also be used to develop animal models essential to developing and testing vaccines, drugs, and other needed medical countermeasures.

The high-containment laboratories are necessary if we are to produce the scientific advances needed to develop medical countermeasures against bioweapons and emerging diseases. However, recent highly publicized laboratory errors and siting controversies have raised questions about whether the governing framework and standards for biosafety and biosecurity measures are adequate. Since 2005, my colleagues and I at the Center for Biosecurity have been concerned that the expanding number of high-containment laboratories may strain current systems for personnel training in biosafety and biosecurity. We held a meeting at the Center on July 11, 2006, to discuss these issues, the report from which we would like to submit into the record. At this meeting, we heard from distinguished scientists and experts in biosafety, biosecurity, and public health—both proponents of the laboratories, as well as those who oppose the recent expansion. Based on those conversations, we believe that there are several things that can be done to ensure that these new high-containment laboratories are productive and safe and operate with due consideration for their neighboring communities. These actions include expanding biosafety training for researchers and workers coming into high-containment research from less dangerous areas of research; monitoring the safety performance and operational experience of the high-containment facilities; increasing communication between the high-containment laboratories to share operational experiences; and initiating a public engagement effort at the Federal level that clarifies the need for high-containment laboratories.

Currently, operational BSL–4 facilities can be found in Frederick, Maryland; Richmond, Virginia; Atlanta, Georgia; Galveston, Texas; and San Antonio, Texas. There are additional BSL–4 facilities under construction in Hamilton, Montana; Boston, Massachusetts; Frederick, Maryland; and Galveston, Texas. The exact number of BSL–3 laboratories in the United States is not known, however an NIH-sponsored survey estimates that there are 277 distinct facilities with BSL–3, with about 600 individual laboratories, and a 2007 report from DHS and HHS states that 633 high-containment laboratories are registered in the Select Agent Program. In addition, 13 BSL–3 laboratories are being built specifically for biodefense research, principally funded by the National Institute of Allergy and Infectious Diseases (NIAID).

It should be noted, however, that high-containment laboratories are being built all over the world at a rapid pace. For example, there were 16 BSL–3 laboratories brought on-line in India in 2006 alone. This expansion is due in part to concerns about SARS and avian influenza, but also because of a recognition that bioscience is a key economic driver for the 21st century: in the US, the biopharma industry produced $188 billion in revenue and 400,000 jobs in 2004 alone. The model that the U.S. sets in operating these high-containment laboratories productively yet safely should provide leadership to other countries heavily investing in biotechnology and pathogen research.

Promoting safety, security, and scientific innovation in the biological sciences has been a challenge undertaken by the government and the bioscience community since 2001. It has led editors of scientific journals to come together in 2003, with the goal of reducing the likelihood that legitimate bioscientific research could be used for malevolent ends. It has led to the forming of the National Science Advisory Board for Biosecurity, chartered in 2004 within NIH. Government and university researchers have also participated in fora intended to diminish the risks and maximize the benefits of new areas of bioscience, such as synthetic genomics. While bioscience promises great strides in enhancing quality of life through the development of medicines and vaccines, it is a powerful technology that must be used safely if we are to enjoy its benefits.

Biosafety protection is designed to be flexible. In the U.S., biological laboratory research can be categorized by its safety level; Biosafety Levels (BSL) 1 through 4. In this testimony, we use the term high-containment to refer to work performed in the two highest levels, BSL–3 and BSL–4. BSL–3 laboratories are used to study biological agents that are potentially lethal and transmissible by the aerosol route and that require special safety design features, such as sealed windows and specialized ventilation systems. BSL–4 laboratories are typically used to study lethal agents for which no vaccine or therapy is available. They incorporate the BSL–3 laboratory safety features, plus additional safety features such as full-body suits ventilated by life-support systems.

In general, the biosafety requirements needed to protect researchers are dictated by the specifics of a biological experiment and are designed to be flexible. For example, an experiment that could normally be safely performed at a low biocontainment level may need additional biosafety protections if the researcher must handle a large volume of infectious material. This flexible system for applying biosafety protections requires researchers to weigh risks as they work. This is a necessity for bioscience research; hard-and-fast regulations for every situation are difficult to develop, as these researchers are not working on one repetitive process that can be fine-tuned but are constantly exploring new scientific ground. The researchers need to use informed judgment.

Biosafety guidelines, such as the Biosafety in Microbiological and Biomedical Laboratories Manual published by the CDC and NIH are thus intended to inform the judgment of researchers, biosafety officers, and others who advise on biosafety, so that biosafety protections can be applied where they are needed. However, some biological organisms are more typically worked on in one safety level versus another: infectious Ebola and Marburg viruses are researched in the highest level of containment, BSL–4; SARS is typically worked on in BSL–3; and Bacillus anthracis, the causative agent of anthrax, is typically safely worked on in BSL–2.

Biosafety training program expansion for researchers entering high-containment. As the new high-containment laboratories become operational in the coming years, additional qualified staff will also be needed. As indicated in our report last year, we have concerns that the usual methods of biosafety training for high-containment research—that is, intensive one-on-one training within a mentor-apprentice relationship—will not be sufficient to handle the influx of researchers and technicians into the field. Developing core competencies and standards for new staff could be a useful and important way to train new staff on safety practices. It could also conserve the experienced mentors’ valuable time and abilities and shorten the time it takes for the labs to become productive.

To develop the workforce, NIH could assess how many people will require training for their work in the high-containment laboratories, and develop and fund programs that can supplement on-the-job training. An assessment may be necessary, as not all of the new hires for a laboratory will work in high-containment conditions. For example, it is estimated that the Boston University National Biocontainment Laboratory will create 600 jobs, but not all of those new employees will work in high-containment conditions.

Biosafety officers, already required at every high-containment facility, will also be needed in greater numbers. Biosafety professionals can help researchers determine the best biosafety procedures and practices for laboratory-specific, experiment-specific containment decisions, so that the researchers can be productive and safe. Biosafety officers can also provide on-the-job biosafety training. NIH could work with the American Biological Safety Association, the biosafety professional organization, to determine credentialing standards required for work in high-containment laboratories. This may help to ensure that biosafety officers are knowledgeable resources for the researchers in these labs.

Monitoring safety performance of high-containment laboratories. With the laboratory expansion, a systematic analysis of safety issues and operational problems in high-containment laboratories can help to ensure that the laboratories are operating safely. Currently, reporting of laboratory-acquired infections is required for all select agents, those pathogens that require clearance to possess under the Select Agent Rule as defined by 45 CFR 72, whether they occur at BSL–2, –3, or –4 laboratories. NIH grants also stipulate that institutions report any serious accidents or research-acquired infections. However, many of the experts we consulted thought nonlethal infections were underreported, and operational problems or “near misses” were generally not reported.

Without reporting, and without analysis of these incidents, lessons cannot be learned from the experience. Laboratory procedures cannot be analyzed in light of the accidents, so that future accidents can potentially be avoided. To correct this situation, disincentives to reporting should be removed, to encourage researchers and their institutions to report and take corrective action.

Generally, there is a disincentive to report acquired infections and other mishaps at research institutions. Infections lead to negative publicity and scrutiny from the granting agency, adversely affecting future research funding. In addition, after a scientist acquires an infection in the laboratory, neither the scientist nor the laboratory wishes to advertise the mistake. These barriers need to be cleared so biosafety can be enhanced through shared learning from operational experiences, and also so the public may be reassured that accidents are being thoroughly examined and contained.

One possible model for high-containment laboratories to emulate is the reporting mechanism used for aviation incidents, wherein airlines can contribute operational experience without fear of regulatory action. Mistakes are analyzed and learned from, but they are not attributed to individuals (except when mistakes result from criminal actions, such as drunkenness). Institutional anonymity may also be required in order to get robust reporting from research institutions. Procedures would need to define thresholds and mechanisms for reporting if an accident poses a danger to the community surrounding the laboratory, however.

There are other potential models for the high-containment labs from the nuclear and chemical industries. The Institute of Nuclear Power Operations (INPO), formed after the Three Mile Island accident, emphasizes personnel training, safety management, and lessons learned; and Responsible Care, formed after the Bhopal tragedy, is a voluntary initiative of the chemical industry to share lessons learned. These models are from for-profit enterprises, underlining that any reporting system will be expensive. Another possibility could be a reporting clearinghouse, where operational experiences would be posted and available for outside analysis.

Ultimately, it is the laboratory director's responsibility to ensure that all laboratory personnel are properly trained to do research safely in high-containment. Yet, the institution where the research takes place may be responsible for ensuring that the head of the laboratory, the staff, and the lab environment conforms with biosafety requirements and accepted practices. The CDC or NIH could monitor proactively whether biosafety is being managed at those institutions where Federal money pays for the research and infrastructure.

High-containment laboratories and sharing lessons learned. Mechanisms to enable and encourage inter-laboratory training and information exchange will be important for these laboratories. Currently, the Select Agent Rule and concerns about legal liability may have inadvertently become barriers to learning across high-containment research facilities. Under the Select Agent Rule, as defined by 45 CFR 72, HHS and USDA keep lists of pathogens that require select agent clearance. The rule regulates the possession, use, and transfer of those agents; imposes security requirements for the facility in which the work will be performed; requires inspections; and can impose criminal and civil penalties on those who do not adhere to the Rule. In addition, security risk assessments are administered to individuals who work with select agents by the Department of Justice, a process that is renewed every five years. Once cleared, an individual is allowed to work with a specific biological agent, but only within a specific laboratory. The specificity of this clearance procedure inhibits the practical exchange of safety-related information and techniques between high-containment laboratory researchers, by preventing, for example, a technician in one laboratory from demonstrating techniques in another laboratory without going through a separate lengthy clearance process.

In addition to clearance barriers, the perception that laboratories will be liable for accidents that occur to scientists visiting for training purposes may have prevented some training opportunities from taking place. This should be addressed so that experienced scientists and technicians can more easily demonstrate techniques and safety procedures developed in one laboratory to another. This could speed up the process for new laboratories to become productive; it could maximize the use of specialized facilities of some laboratories; and it could result in increased safety of the research.

Public engagement as a Federal priority for high-containment labs. NIAID has a great deal of information about the new high-containment laboratories on its website, but direct engagement with the communities where the laboratories are being built is handled by the institution proposing the laboratory. Thus, the strategies and outcomes of public engagement, as well as the transparency of laboratory operations to the public, have varied considerably. This has undoubtedly exacerbated the controversy surrounding the siting and operation of these laboratories, particularly in the face of highly publicized laboratory errors. While individual facilities bear final responsibility for their relationships with their neighbors, NIAID could have a clearer mechanism to engage with the public about the siting and operation of these laboratories, beyond the NEPA process. It may help if there is a more aggressive and proactive Federal effort to standardize public engagement and transparency of operations for high-containment laboratories and to direct funds to this purpose.

A public engagement program could address the concerns that have surfaced in siting high-containment laboratories. Often, proponents of the labs interpret protests against the laboratories as a lack of understanding of science: however, the concerns about the labs are varied. For example, there have been concerns that the labs would become a terrorist target, or that the laboratory would not provide jobs to the community. The communites' concerns could be actively addressed both by HHS and NIAID and by the institution sponsoring the laboratory.

These high-containment laboratories should be a critical part of the research infrastructure for understanding the mechanisms of pathogenicity, as well as developing and testing medical countermeasures. However, as these labs come online, so should new systems for training of personnel, monitoring safety performance, and engaging the public. Experience has shown that proactive steps such as these can lead to more effective and cost-efficient safety management than burdensome requirements imposed following a serious accident. A new governance framework could enable the laboratories to operate more safely, with consideration for their communities, and it could help the laboratories fulfill their intended purpose of protecting the Nation against natural and man-made biological threats.

Mr. STUPAK. Thank you. Dr. Pearson.

STATEMENT OF ALAN PEARSON, DIRECTOR, BIOLOGICAL AND CHEMICAL WEAPONS CONTROL PROGRAM, CENTER FOR ARMS CONTROL AND NON-PROLIFERATION

Mr. PEARSON. Well, thank you for inviting me to testify today on behalf of the Center for Arms Control and Non-Proliferation. Since 1980, the Center has been working to protect the American people from the threat of nuclear, chemical and biological weapons and we see the issues being considered here today as integrals to achieving that goal.

Over the last 6 years, the Federal Government has dramatically increased U.S. research and development activity and infrastructure focused on biological agents that could be used as biological weapons.

The data are clear. Annual R&D funding is up six-fold since 2001. More than two dozen new high-containment facilities, which we have heard about, funded specifically to work with such agents. Over 15,000 individuals approved to work with such agents. This expansion recognizes our need for a national biodefense program but it is not necessarily an unalloyed good. It also creates risks to laboratory personnel, public health and national security. Basically, and we have heard this already today, when more dangerous research is performed by more people in more locations, there are simply more opportunities for significant biosafety or biosecurity breaches to occur.

I would like to just make one point clear. The risk is not limited to the BSL–4 labs, although that is usually the focus of the attention. There is actually good reason for concern that the risk may be even greater at some of the BSL–3 labs. The most obvious risk is that of the lab accident. A second particularly acute risk that I would like to bring to your attention is that the very labs designed to protect us against biological weapons could become a source for them. The easiest way for a sub-state enemy, such as Al-Qaida, to obtain a bioweapons capability will be for it to penetrate an existing research project that uses these agents. Nor should we ignore the possibility that a U.S. biologist working in one of these labs could become disgruntled or even turn rogue.

Some types of contemporary pathogen research taking place in these labs increase risk further still. For instance, efforts to deliberately enhance the virulence or transmissibility of pathogens, to understand how they cause disease, are inherently more risky than experiments of the past. They are also dual-use in nature, the knowledge and materials generated by the experiments can be used for either hostile or peaceful purposes. And a particular concern in this regard is threat assessment research, which is typically classified research that involves the exploration of offensive aspects of biological weapons agents and delivery mechanisms for defensive purposes.

Looking internationally for just a moment, each of these concerns that you are hearing about becomes amplified. Our actions here, taken for the best of intentions of protecting our Nation, also provide a plausible justification for others to do the same. So there is a critical need for rigorous oversight and maximal transparency of these facilities and activities.

What I would like to highlight here then are just a few of the tools that our Federal Government needs in order to ensure that oversight is stronger. First, Congress should mandate the establishment of a universally mandatory and transparent incident reporting system. Second, Congress should mandate a national licensing system and registry for all level 3 and level 4 facilities in the United States, including an integrated and effective auditing process. Licensing and registration are key to both effective oversight and comprehensive strategic planning. Third, Congress should mandate institutional biosafety committee review of all research projects involving bioweapons agents and other high-risk pathogens and activities. Fourth, Congress should make these requirements legally mandatory for all institutions, government, academic and private, not just those receiving funds from NIH and they should apply also to all relevant research, whether that research is classified or not. Fifth, compliance requires effective monitoring and enforcement. A law not monitored and enforced may be little better than a voluntary guideline. Congress should seriously consider consolidating all CDC and NIH, responsibilities and authorities relevant to monitoring and enforcing the suggestions I just made into a single office located within the Office of the Secretary of Health and Human Services. Sixth, Congress should mandate comprehensive inter-agency needs and risk assessments to determine our current and anticipated U.S. needs for high-containment facilities and the potential risks associated with them. Until such assessments are completed and reviewed, there should be no funding for any additional facilities. Last, Congress should modify section 351(a)()h of the Public Health Service Act to more narrowly and accurately define necessary and appropriate requirements for withholding information about activities involving these agents. As currently written, that section is hurting biosafety, biosecurity and national security by impeding public accountability of our institutions and Federal agencies and by reducing our ability to reassure others that our R&D activities comply with our obligations under international law. Thank you.

[The prepared statement of Mr. Pearson follows:]

Written Testimony of Alan M Pearson
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Center for Arms Control and Non-Proliferation, Washington, DC

Submitted for the Record to the
House Energy and Commerce Committee
Subcommittee on Oversight and Investigations

For the Hearing "Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States"

October 4, 2007

Thank you for inviting the Center for Arms Control and Non-Proliferation to discuss issues related to the recent and rapid expansion of high containment laboratory research and research capacity in the United States. Since 1980, the Center has been working to protect the American people from the threat of nuclear, chemical and biological weapons. Here I discuss some of the public health and national security risks associated with the expansion of bioweapons-related research and development, and I propose some steps our nation can take to help mitigate these risks.

Over the last six years, the Federal government has dramatically increased US research and development activity and infrastructure focused on biological weapons agents. This continuing expansion promises new capabilities for detecting and responding to potential bioweapons attacks and natural infectious disease outbreaks. It also creates increasing risks to laboratory personnel, public health and national security. In order to reduce these risks, we need

- Strong and effective biosafety and biosecurity practices and oversight mechanisms
- Transparency to guarantee public accountability, and
- Rigorous and transparent interagency needs assessment and strategic planning to match research and infrastructure capacity with national needs.

Our current biosafety and biosecurity system is plagued by significant and systemic weaknesses, inadequate oversight and transparency, and a lack of rigorous interagency needs assessment and strategic planning. Unless corrective action is taken, the risks to our nation and its people from accidental or deliberate disease outbreaks arising from our own activities and institutions will continue to rise. The US biosafety and biosecurity system needs to be made more coherent, more comprehensive, more effective, and more transparent:

- Congress should mandate, and DHHS and USDA should develop, biosafety and biosecurity training standards and minimum core competencies for work with high-risk biological agents, including a plan for meeting national training needs

- Congress should mandate, and DHHS and USDA should develop, operate and maintain a universally mandatory and transparent Biosafety/Biosecurity Incident Reporting System

- Congress should mandate, and DHHS and USDA should develop, establish and maintain a national licensing system and registry for all BSL-3 and BSL-4 facilities in the United States, including an integrated and effective auditing process

- Congress should mandate institutional compliance with the performance-based guidelines contained in *Biosafety in Microbiological and Biomedical Laboratories* and the NIH Guidelines

- Congress should mandate independent Institutional Biosafety Committee (IBC) review of all research projects involving bioweapons agents and other high-risk pathogens and activities, not just those involving certain categories of rDNA research

- Congress should make all three of the above requirements legally binding for all institutions – government, academic and private – not just those receiving funds from NIH, including all institutions which conduct classified research activities, so as to help ensure universal application of and compliance with these requirements

- DHHS and USDA should define and fund the development of the training and infrastructure needed to implement such IBC review

- Congress should consider consolidating all CDC and NIH OBA responsibilities and authorities relevant to implementing, monitoring and enforcing the above requirements into a single office located within the Office of the Secretary DHHS, or in some other way improving the coherence of the US biosafety and biosecurity system

- Congress should require an annual report from DHHS and USDA detailing their efforts to implement and enforce all of the above requirements

- Congress should modify Section 351A(h) of Title III of the Public Health Service Act in order enhance accountability by more narrowly and accurately defining necessary and appropriate requirements for withholding information about activities involving potential bioweapons agents

- Congress should mandate that the Executive Branch work to promote the adoption of these strengthened biosafety and biosecurity requirements more broadly by other countries

- Congress should mandate comprehensive national needs and risk assessments for the continuing increases in the number of high containment research facilities and the number of institutions and individuals conducting bioweapons-related research

All too often in current debates, a wedge is placed between supporting important life sciences research on the one hand and preventing accidents and the malevolent use of the life sciences on the other. In fact, both are possible and necessary. Effective oversight and transparency of life sciences research activities contributes to enhancing public health and national security; it is the lack of adequate and appropriate oversight and transparency which adds to the risks we face today. Experience shows that stronger oversight of high-risk research and research facilities can be designed and implemented. (Davidson, et al, Science, 316, 1432-33, 2007; Lentzos, Biosecurity and Bioterrorism, 5: 55-61, 2007; Tucker, Disarmament Diplomacy, 84, Spring 2007). Regulations will need to be carefully designed to ensure that they reduce risk. They will also need to go beyond what is currently in place in the United Sates today.

Bioweapons-related research and development activities and capacity are increasing dramatically

For the last two years, the Center for Arms Control and Non-Proliferation has analyzed federal funding for bioweapons-related activities (see Appendix A for our analysis of the FY2008 budget). Our analysis shows that funding for bioweapons-related research and development has increased from approximately $583 million in FY2001 to over $3 billion in FY2007. For FY2008, the Bush Administration has requested over $3.3 billion for such research and development. The increase has been particularly dramatic for civilian (i.e. non-DOD) research and development, which has gone from $135 million in FY2001 to nearly $2.4 billion proposed for FY2008. In sum, from FY2001 through FY2007, nearly $17 billion in federal funds have been spent or appropriated for bioweapons-related research and development activities.

Of this $17 billion, over $1.7 billion has been appropriated for the construction of new high containment research facilities for bioweapons-related research. By high containment facilities I mean facilities that are designed for work with agents that may cause serious or potentially lethal disease through exposure to aerosols (called Biosafety Level 3 or BSL-3 facilities) and facilities that are designed for work with agents that pose a "high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy" (called Biosafety Level 4 or BSL-4 facilities).

Our preliminary analysis shows that, as a result of this funding, high containment research and development infrastructure is expanding rapidly along at least three dimensions:

1) **The absolute number of facilities.** Prior to 2002, there were three significant BSL-4 facilities in the United States. Today twelve are in operation, under construction, or in the planning stage. When completed, there will be in excess of 150,000 square feet of BSL-4 laboratory space (as much space as three football fields). The number of BSL-3 labs is also clearly growing, but ascertaining the amount of growth is difficult in the absence of accurate baseline information. There are at least 600 such facilities in the US.
2) **The average size of such facilities.** The average size of a new BSL-4 facility is three times that of those which existed previously. BSL-3 space is similarly growing. According to a June 2005 report, 66% of institutions responding to a survey on BSL-3 capabilities had <1000 square feet of BSL-3 space; in the ten new BSL-3 facilities for which such data is publicly available, average BSL-3 space is nearly 12,000 square feet.[1] (Constella Health Services, "Survey for Determining the Location, Capacity and Status of BSL-3 Laboratories," June 2, 2005). One very large and notable BSL-3 facility not included in the above calculation, a private facility identified as "BCF-01" in a January 2007 DHHS/DHS report to Congress on high containment facilities, recently expanded from 36,000 net square feet of BSL-3 space to 88,000 net square feet.
3) **The number and size of facilities capable of conducting aerosol exposure studies in mammals including non-human primates.** Specific data are not available, but the DHHS/DHS report indicates a substantial increase in both the number and size of such facilities. Such studies can raise particularly significant biosafety risks. Secrecy surrounding such facilities can cause significant international concern about the intent of their activities.

The current expansion in high containment infrastructure appears to have occurred in the absence of rigorous interagency needs assessment and risk-benefit analysis. For instance, the February 2002 NIAID Strategic Plan for Biodefense Research simply called for the establishment BSL-3 and BSL-4 capability at 6 – 12 regional Centers of Excellence for Bioterrorism and Emerging Infectious Disease research, but provided no explanation for how it arrived at that number. NIAID has exceeded these recommendations, funding the construction of 13 regional BSL-3 laboratories and 2 national BSL-3/BSL-4 laboratories, and building three additional intramural BSL-3/BSL-4 facilities.

Yet, in mid-2004, 8 months after announcing the awards for 11 of these facilities, NIAID officials acknowledged that they couldn't say for sure whether too much space, at least at BSL-3, had been planned because there was no accurate inventory of existing BSL-3 labs. A committee of federal agencies was conducting a national needs assessment, and officials said that until it was completed about one year hence, they would not know "whether we need six times more, 12 times more, or 100 times more" space (The Scientist, May 24, 2004).

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[1] Some of this increase may reflect design changes made to facilitate workflow in BSL-3 facilities, such as moving experiment set-up and other functions incidental to the experiment itself into the BSL-3 laboratory.

The needs assessment was probably that delivered by DHHS and DHS almost three years later, in January 2007 ("Report Regarding Biocontainment Facilities, A Report to Congress," January 2007). It concludes that prior to the recent expansion of high-containment facilities, existing high-containment aerosol challenge and GLP capacity would likely have "limit[ed] progress in current development and acquisition programs." However, the current expansion "should significantly increase model development and testing capacity." The report does not assert that any further expansion is necessary at this time, implying that there will soon be adequate high containment capacity in the United States. No assessment was made regarding the distinct possibility that there might be an **overcapacity** of BSL-3 and BSL-4 facilities.

Nor does the report appear to consider the new facilities that have or are being built at the CDC, DHS, DOD and DOE. To be sure, some of these facilities are necessary. At the time of the anthrax attacks in 2001, the need for additional high level containment facilities to meet research needs for both biodefense and naturally occurring infectious diseases was clear. But in replacing these aging facilities, the Federal government is increasing its own BSL-3 and BSL-4 capacity 10-fold or more.

As already noted, no US government agency knows the identity and critical details about every BSL-3 and BSL-4 facility in the United States. A June 2005 report by NIAID stated that at least 277 facilities in 46 states had a total of 598 distinct "BSL-3 capable laboratories." Of these, 7 had capabilities for non-human primate studies, 21 for aerobiology studies and 57 had FDA Good Laboratory Practices (GLP) capability (the extent to which these capabilities overlapped was not clear in the report). The January 2007 DHHS/DHS report found that 204 "entities" registered with the CDC Select Agent Program had a total of 633 distinct BSL-3 and BSL-4 "facilities." Of these, 39 had the "capacity to conduct the animal studies necessary for medical countermeasure testing." The number having capability for aerosol-challenge studies in animals including non-human primates, and the number that are GLP compliant, were not identified. The number having both capabilities was identified as being either three or six, depending on how one interprets the report. The report does not include any facilities not registered with the CDC Select Agent program, such as those whose work with biological agents (such as H5N1 highly pathogenic avian influenza virus) is covered only by USDA or facilities that conduct BSL-3 or BSL-4 level work only with non-select agents. (Bioweapons agents are not the only pathogens handled in high containment facilities. Some types of work with, for example, multi-drug resistant *Mycobacterium tuberculosis*, the SARS coronavirus, and certain influenza viruses are also conducted in BSL-3 or BSL-3+

facilities. While work on such agents is not the reason for the recent expansion of high containment facilities, considerations of biosafety do extend beyond bioweapons agents per se.)

Neither report identifies specific facilities or entities having BSL-3 and BSL-4 capabilities. Neither provides an indication that information such as the age and condition of the facilities and the identity of the agents studied in them was collected. Neither assesses the overall operational status of the existing facilities. The data collected for the NIAID report were presumably destroyed as planned 120 days after the report was issued. Thus, NIAID likely no longer has a record of which facilities have BSL-3 capabilities. The Sunshine Project currently maintains the most comprehensive, publicly available list of BSL-3 and BSL-4 laboratories in the United States.

The content, discrepancies and gaps in these two reports indicate that no US government agency maintains a comprehensive database of BSL-3 and BSL-4 laboratories in the United States. This problem is highlighted by the existence of a third report, from researchers at Los Alamos National Lab and elsewhere, that there were over 1400 BSL-3 facilities in the United States as of 2004 (Sassone, et al "Review and Assessment of New Biological Safety Level 3 (BSL-3) Facilities," 2004).

As far as can be determined, a thorough interagency needs assessment and risk-benefit analysis has still not been conducted. None of the above-mentioned reports assess the overall operational status of existing BSL-3 and BSL-4 laboratories, or the degree to which existing capacity is being utilized. The 2007 report comes closest, but focuses on the narrower question of GLP-compliant high-containment animal (including non-human primate) aerosol challenge capacity. The lack of a registry containing fundamental data on existing high containment facilities will continue to significantly impair planning.

The Committee may want to look into these issues further. The may also want to look into issues surrounding the siting of these laboratories, which have caused concerns in some local communities.

Research and development capacity is increasing in another extremely important way – the number of individuals who are working with bioweapons agents and other high-risk pathogens. The 15-fold increase in non-defense bioweapons-related research and development funding has generated a major increase in research and development activities, and in individuals having access to bioweapons agents. As of August 2007, over 14,400 individuals at 327 registered entities were approved by the CDC for access to one or more bioweapons agents (personal communication from Cassandra Willyard, Nature Medicine). Over 7200 individuals are approved to work with anthrax alone (Hartford Courant, Oct 8, 2006).

Finally, it is important to note that the recent expansion includes an increase in classified bioweapons-related research, and in activities that fall under the nebulous and ill-defined label of sensitive but unclassified. In particular, the Department of Homeland Security is responsible for conducting threat assessment research. Such research involves the exploration of offensive aspects of biological weapons agents and delivery mechanisms for defensive purposes. Much of this research is clearly sensitive, and some of the results may need to be classified. The number of threat assessment projects currently underway is not publicly known, but will surely increase once DHS' National Biodefense Analysis and Countermeasures Center (NBACC) being built at Ft. Detrick, Maryland, is operational. The Defense Department also conducts a significant level of classified bioweapons-related research and development, and the Department of Health and Human Services has also been given original classification authority, although it has not yet utilized that authority extensively.

The expansion in bioweapons-related research and development funding and activities is not over. The current level of funding is supporting research and development activities that, for the most part, do not yet use the new high containment facilities being constructed. As these facilities come online, we can expect that bioweapons-related R&D funding and activities will increase still further. The number of researchers with access to bioweapons agents will probably continue to expand if all of our new high containment facilities are to be fully utilized. According to a USAMRIID official "[w]hen I look at the capacity for studies" being built in this US, the number of BSL-qualified researchers "has to be five-fold bigger than we [have] now." (The Scientist, May 24, 2004). At the time approximately 11,000 individuals were registered with the CDC (Baltimore Sun, June 27, 2004).

The expansion of high containment research and research facilities is generating increased risk to researchers, the public health, and national security.

The biosafety and biosecurity risks associated with the dramatic and ongoing expansion of high containment research and research facilities are both real and growing.

By "biosafety risks" I mean those risks related to the protection of laboratory personnel and the outside community and environment from the potential effects of unintentional exposure to or accidental release of hazardous pathogens and toxins. By "biosecurity risks," I meant the risks related to the protection of individuals, communities and nations from the potential consequences of the deliberate theft, diversion, or use of biological agents to cause harm. The report *Globalization, Biosecurity and the Future of the Life Sciences*, released early last year by the National Academies, warns that harm can arise from both the malevolent and the careless or negligent use of biotechnology and the life sciences. Biosafety and biosecurity are two parts of a whole, and the mechanisms and processes needed to mitigate biosafety and biosecurity risks are complementary and overlap significantly.

Concerns about biosafety are well-founded. The circumstances surrounding recent laboratory accidents, such as infections of laboratory workers with the causative agents for tularemia (at Boston University; Boston Globe, Jan 19, 2005), brucellosis and Q fever (both at Texas A&M; Dallas Morning-News, June 26, 2007), provide the most direct indication that not all existing high containment laboratories are being operated as safely as possible. Not only are accidents occurring, but there are widespread deficits in biosafety training of laboratory personnel and underreporting of biosafety incidents, both of which contribute to elevating biosafety risk. For instance, a 2006 report by the DHHS Inspector General revealed deficits in training at 3 of 15 universities inspected (Daniel Levinson, "Summary Report on Universities' Compliance," A-04-05-02006, June 6, 2006). CDC has typically recorded about 20 accident reports per year since 2004, but has received 32 reports since April 2007 (Science, Sept 28, 2007). Until recently, the University of Texas had reported only 3 of 15 reportable biosafety incidents since January 2000 to federal authorities (American-Statesman, Sept 9, 2007). UT Medical Branch in Galveston recorded 17 cases of "potential exposure" to infectious agents over the last five years, but reported only one (Dallas Morning News, July 4, 2007). And since 2002 there have been dozens of exposures to hazardous biological agents in Texas universities for which there is no reporting requirement (Dallas Morning News, July 27, 2006). It is doubtful that these problems are restricted to Texas alone. Finally, as discussed further below, there are significant and systemic problems with the Institutional Biosafety Committee system put in place to reduce biosafety risks.

Concerns about biosecurity risks associated with the current expansion are also well-founded. While the numerous biosecurity failures at Texas A&M stand out, they are not alone. The June 2006 report by the DHHS Inspector General found that fully 11 of the 15 institutions working with bioweapons agents had inadequate security controls and other weaknesses which "could have compromised the ability to safeguard select agents from accidental or intentional loss." This finding came after an earlier investigation of 11 universities found similar defects at each. The Inspector General has apparently levied fines ranging form $12,000 to $150,000 on 9 institutions **and** companies for biosecurity breaches (Science, Sept 28, 2007).

The occurrence of these biosafety and biosecurity incidents does not alone necessarily mean that the level of risk is increasing. But there are additional and very good reasons for believing that it is.

First, as more research is performed with dangerous pathogens by more people in more locations, there are more opportunities for biosafety or biosecurity breaches to occur. It is quite clear that in the absence of countervailing efforts to mitigate risk, the potential for a high-consequence accidental or deliberate release of a dangerous biological agent will increase at least linearly with the expansion in the number of high containment facilities, the amount of bioweapons-related and other high-risk research activities, and the number of individuals working with bioweapons agents and other particularly dangerous pathogens.

The increase in the number of people working with biological weapons agents is particularly worrisome from a biosecurity perspective. To make an effective biological weapon, i.e. one that is capable of killing not just a few, but large numbers of people, requires three essential ingredients – materials, equipment, and expertise. Contrary to what is commonly stated in the media and by some biodefense boosters, it is not so easy to create an effective biological weapon. It can't be done by one person with high school knowledge of biology working in a cave. Rather, the easiest way for a sub-state adversary such as Al Qaeda to acquire a bioweapons capability is for it to penetrate an existing research project that uses bioweapons agents, obtaining both agents and training. Nor should we ignore the possibility of a biologist becoming a terrorist. As Vice Admiral Robert Murrett, Director of the National Geospatial Intelligence Agency, recently noted, biological weapons are best tracked by monitoring scientists with the expertise to make them. According to Murrett, this is posing a major challenge for the intelligence community. (Intelligence official: Bioweapons scientists tough to track, Associated Press, Sept 26, 2007) It is worth asking how the large increase in the number of bioweapons scientists in the US is affecting the IC's ability to meet this challenge.

Second, the speed of the current expansion is probably further increasing the risk by stressing and possibly even overwhelming our current national capacity for rigorous biosafety and biosecurity training of the individuals working in the new high containment laboratories. The likely result will be a decrease in the average level of training and experience in working in these facilities. It is unclear whether the NIH or any other agency has begun to assess workforce training needs, or has begun to implement programs to meet those needs.

Third, the direction in which some pathogen research is expanding today increases the risk further yet, as researchers conduct experiments which are inherently more risky than those of the past. Researchers are sometimes now trying to enhance the virulence of pathogens to determine what makes them lethal. They are trying to enhance the transmissibility of pathogens to understand what makes them contagious and what makes them able to pass from one host species to another, such as from chickens to humans. For instance, researchers at the CDC and elsewhere are now conducting experiments with the H5N1 avian influenza virus to see if they can convert it to a form that is more easily transmitted from one person to another. While some of this research may bring benefits to health and society, it also clearly carries substantial safety risks.

Some of it also carries substantial security risks. Such research is very often inherently dual-use – the materials and knowledge derived from the research can be used for either harmful or peaceful purposes. The dual-use problem is a growing concern of those who think about preventing and responding to biological attacks. A good illustration of this issue is the recent successful recreation from scratch of the

1918 influenza virus, perhaps the single most deadly virus in human history. This virus was extinct until researchers from the CDC and other US institutions brought it back from the grave (Tumpey, et al, Science 310: 77-80, 2005). Not only have we now created a new and fearsome potential bioweapons agent, but by publishing the sequence of the viral genome we have provided much of the information needed for its recreation by others. Moreover, we have provided a plausible reason for them to do so: whether released deliberately or by accident, if the 1918 flu gains a foothold, it will know no borders. Everyone will be at risk. Yet not publishing such information once we've generated it might be a bigger problem, for it might suggest to some nations that we are withholding information critical to their own security and that of their citizens. It might leave the impression that we are actually up to no good.

Might we in fact be turning such work into the type of glamorous fetish and matter of institutional and national pride that could contribute to an unnecessary proliferation of high-risk research? For instance, should we be concerned when the scientific director of the facility in which the 1918 virus was recreated for a second time says "[w]e're very proud of this work ... it demonstrates our capabilities and that we're an important piece of the science machinery of the world." (Canadian Press, Jan 17, 2007). I do not mean to suggest that particularly risky activities such as these are common or widespread. They are not. But they are growing in frequency. These are difficult problems to solve, and they clearly indicate a need for strong and publicly accountable oversight of dual-use research.

Fourth, similar but possibly even more acute biosafety and biosecurity risks are associated with threat assessment research. Not only are we exploring offensive aspects of known bioweapons agents, we are also now exploring and possibly trying to create new biological threat agents. The rationale for these efforts is that we are engaged in a biological "arms race" between protective measures and potential malevolent applications of life sciences research and technology. While this "capabilities-based" approach to threat assessment is not without merit, it is also fraught with substantial danger. Where is the line between legal and illegal activities under the Biological Weapons Convention? How can we ensure that we aren't engaging in an arms race against ourselves, and that our attempts to keep up with the "threat curve" don't simply push that curve forward faster? Since other nations will recognize the unavoidably dual-use nature of our activities, will they misperceive our efforts as potentially offensive in nature, and respond by carrying out their own, similar activities? At the very least, by undertaking such research we will be providing a plausible justification for others to do the same. While some threat assessment research is important, there must be a rigorous process in place for ensuring that only those projects that are absolutely necessary are conducted, for mitigating risk, and for demonstrating that the work complies with our international obligations under the BWC. Strengthening oversight of this expanding and highly consequential area of dual-use research is essential.

All of these factors are increasing biosafety and biosecurity risks as our current expansion continues. None of them, nor even all combined, argue decisively against some expansion of high containment bioweapons-oriented research and infrastructure. However, they do highlight the need for a fundamental re-examination of the extent of our expansion and, more generally, of our national strategy for confronting biological threats. And they make a compelling case for effective measures to mitigate the risks we are taking and the risks associated with the more general advancement of the life sciences.

Our biosafety and biosecurity system is not adequate to meet the increased risk

No activity involving a dangerous pathogen or toxin will ever be risk free. However, risk can be minimized through the combination of effective biosafety and biosecurity practices, management, oversight, enforcement, and accountability.

Unfortunately, the current US biosafety and biosecurity system has significant and systemic weaknesses. Despite the dramatic expansion in high containment research and research capacity, there has been no enhancement of biosafety oversight and regulation. Indeed, there are almost no legally binding biosafety rules or regulations, there is no comprehensive biosafety law, and there are no universally applicable biosafety guidelines. While there are biosecurity laws and regulations, there are significant gaps in those regulations, and there has been only partial and inadequate enhancement of biosecurity oversight and enforcement.

There are three distinct mechanisms in the United States that address biosafety and biosecurity: the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines), including the Institutional Biosafety Committee (IBC) system established by the Guidelines; the Select Agent Rules promulgated by APHIS and the CDC under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and several regulatory standards promulgated by the Occupational Safety and Health Administration (OSHA) (for a detailed review of each of these mechanisms, see Appendix B). Each has gaps and weaknesses.

The NIH Guidelines.

The NIH Guidelines, and the IBC system established by them, provide the only federally mechanism for increasing the likelihood that research projects adhere to biosafety guidelines. However, the Guidelines apply only to research projects involving recombinant DNA (rDNA). With two very narrow exceptions, there is no federal requirement for IBC or any other review of work involving bioweapons agents or other dangerous pathogens unless such work also involves recombinant DNA. Moreover, the Guidelines apply only to those institutions that receive NIH funding for rDNA research, and those institutions that receive funding from other federal agencies who have decided to adopt the Guidelines, such as the National Science Foundation. In addition, the Guidelines do not carry the weight of law. Instead, failure to comply with the Guidelines can result penalties up to and including the termination of NIH funding for research involving rDNA at the institution. Finally, NIH does not effectively monitor or, when necessary, enforce compliance with the Guidelines.

In 1984, NIH and CDC developed the *Biosafety in Microbiology and Biomedical Laboratories* (the BMBL, now in its fifth edition) to provide guidance and advice to institutions and individuals on the safe handling and containment of infectious microorganisms and dangerous biological materials. Since that time, roughly two-thirds of the approximately 400 institutions with registered IBCs have chosen to assign their IBCs the additional responsibility of reviewing non-rDNA activities involving dangerous pathogens and other hazardous agents (Hackney, 2003). However, as noted by NIH Office of Biotechnology Activities (OBA), "this additional responsibility is assigned entirely at the discretion of the institution."

Recent studies have revealed major weaknesses in the IBC system. For example, a 2003 survey of registered IBCs identified the following problems (Hackney, 2003):

- Limited resources – two-thirds of IBCs had less than one full-time equivalent staff member
- Lack of institutional involvement - nearly half were not required to make formal reports to their institution, suggesting that many institutions do not pay much attention to the effectiveness of their IBCs or their responsibilities under the Guidelines
- Lack of training - 80% of IBC members do not receive training, despite an NIH requirement that institutions are responsible for ensuring that they do
- Insufficient oversight of research – nearly 60% meet two times per year or less (one-third meet only "as needed")
- Inadequate transparency and accountability - 50% do not make their minutes available to the public, in direct violation of the NIH Guidelines

A 2004 study by the non-governmental group known as the Sunshine Project found additional problems, including (Sunshine Project, "Mandate for Failure," October 2004):

- Non-functional IBCs
- Blanket approvals for research, rather than specific project review
- Dramatic variation in the quality of IBC minutes, many of which did not offer "sufficient detail to serve as a record of major points of discussion and the committee's rationale for particular decisions" as required by the Guidelines
- An apparently wide and uneven range of practices and procedures for IBC review of research from one institution to another
- Industry largely escapes from the IBC system altogether

The work of the Sunshine Project has revealed another significant weakness as well – ineffective monitoring, oversight and enforcement by NIH OBA, the office responsible for administering the NIH Guidelines. NIH OBA requires only that institutions file an annual report listing the members of their IBCs together with their biographies. As related in an April 2005 report in the Chronicle of Higher Education, NIH OBA "does not collect IBC minutes to confirm that they are reviewing research, and it does not require biosafety committees to certify that they are in compliance, as it does with institutional review boards." (Institutional review boards are responsible for ensuring human subjects protection in research and are mandated by federal law.) In December 2004, NIH OBA announced that "[i]n the coming year, the NIH will be conducting site visits at selected institutions to obtain further information on IBC compliance with the *NIH Guidelines* and to educate institutions more directly about requirements that apply to the conduct of recombinant DNA research." (Memo from Amy Patterson to All Institutions Receiving NIH Funding, Dec 6, 2004). The outcome of those visits remains unknown. As for enforcement, NIH OBA has no authority to conduct inspections and has rarely if ever exercised its fiduciary power to enforce the Guidelines in anything other than work involving human gene therapy.

The Select Agent Rule

The Select Agent Rule requires that institutions desiring to possess, use or transfer certain "select" biological agents or toxins (i.e. bioweapons agents) register with the Federal government, and that individuals having wishing to have access to such agents or toxins undergo a background security check. They also provide the first universal and legally mandatory federal requirements for institutions to develop, implement and maintain biosafety, security, and incident response training and plans. Nonetheless, as with the NIH Guidelines, there are major weaknesses and gaps.

For example, the Rule applies only to the possession, use or transfer of select agents and toxins. It does not apply to any work with dangerous biological agents that aren't so classified. Further, it does not set minimum standards for the content of the biosafety, security and incident response plans, nor does it require that entities submit their plans to the CDC for review at any time before or after they are certified, a gap that became apparent in the Texas A&M case. As with the case of IBCs, at some entities the plans may be quite good, while at others they may amount to little more than meaningless paperwork. Even more important than failing to ensure that this paperwork is in order, the Rule does not require that research projects involving potential bioweapons agents be subject to institutional review and oversight to ensure that they are being conducted safely and securely. Similarly, it does not require that biosafety level assignments for such work be determined by a risk assessment, or that institutions do anything more than "consider" the recommendations of the NIH Guidelines and the BMBL. Again, the incidents at Texas A&M have revealed some of the potential consequences of this gap that the CDC has known about, and ignored, for years. Yet further, in granting access approval for individuals, the CDC does not require evidence that they are capable of safely and securely handling biological agents. Rather, the Rule requires that the entity's Responsible Official certify that the individuals are competent. This certification requirement is necessary, but is obviously not sufficient for guaranteeing that researchers have the skills they need. It is legitimate to question whether the Rule fulfills the statutory requirement that they ensure "proper training and appropriate skills to handle such agents and toxins." Finally, the Rule fails to define the meaning of "occupational exposure," thereby leaving uncertainty about the comprehensiveness and intent of the mandate to report such exposures. The consequences of this weakness are now widely apparent, as demonstrated by the accident reporting problems at Texas A&M and elsewhere.

Nonetheless, if effectively implemented, monitored and enforced, the Select Agent Rule could provide a reasonable foundation for beginning to strengthen some aspects of institutional biosafety and biosecurity. But it is not being effectively implemented, monitored and enforced by the CDC (this analysis does not consider USDA management of its Select Agent Program). This is apparent in the fact that in two successive reports the DHHS Inspector General has documented no significant improvement in institutional implementation of the Select Agent Rule. It is apparent in the fact that the CDC continues to learn about significant institutional compliance failures from others (a problem the CDC shares with NIH OBA when it comes to non-compliance with the NIH Guidelines). In the case of Texas A&M, either CDC's own inspections repeatedly failed to reveal significant institutional deficits, or the CDC failed to act effectively to correct those deficits. Quiet, informal and non-adversarial consultation with institutions to improve implementation of and compliance with the Select Agent Rule is absolutely essential, but it also must achieve demonstrable success. Can the CDC objectively demonstrate that there has been significant progress in institutional implementation and compliance?

The CDC refuses to make any of its inspection reports public, incorrectly citing a provision of the 2002 Bioterrorism Act as justification (see Appendix D). Thus, it is very hard to independently examine this question. More, very little is publicly known about how CDC conducts its inspections and interprets inspection results, about the competencies of the CDC inspection teams, or about what types of actions CDC takes in response to any weaknesses it finds. What are the standard operating procedures for CDC inspections? Do inspectors have a list of key indicators for determining if a deeper inspection is required? Such a list might both facilitate the inspection process and avoid needless alienation of those institutions that have a good record of compliance. Are more inspectors with better skill sets needed? Will the CDC now re-examine its inspection process? In short, does CDC know what it is doing?

Concerns about the CDC's regulatory abilities are not new. Chairman Stupak raised such concerns as far back as 1999 during a House Commerce Subcommittee hearing on the Threat of Bioterrorism in America. The need for better verification measures to monitor compliance was raised by Senator Feinstein during a Senate Judiciary Subcommittee hearing on Germs and Toxins as Domestic Terrorist Threats in 2001.

And a 2002 performance review of CDC's management of the Select Agent Program by GAO highlighted major deficits in CDC monitoring, inspections, databases and organizational structure (GAO-03-315, Nov 22, 2002). As this review was conducted before the new and significantly expanded Select Agent Rules went into effect, perhaps it is time for GAO to be asked to update its previous study of CDC's regulatory efforts in this critical area.

Finally, there are two significant gaps in the Select Agent Rules that remain completely unaddressed. First, registered institutions have no obligation to report occupational exposures or breaches of primary containment to State or local public health authorities. Second, the Rules, as interpreted by the CDC, provide almost no coverage for synthetic genomes. The recreation of the 1918 influenza virus shows how it has become possible to synthesize or clone DNA encoding the entire genome of a select agent virus and use this DNA to generate the virus essentially from scratch. Yet, the CDC interprets the Rules in such a way that the possession, use or transfer of such DNA is unregulated unless the DNA itself can be considered intrinsically infectious. Only a few of the viruses of bioweapons concern, such as Venezuelan Equine Encephalitis (VEE) and the tick-borne encephalitis viruses, fall into this category.

This means that it is currently entirely legal for an unregistered individual to possess, use or transfer nucleic acids comprising the entire genome, plus all the materials needed to generate infectious virus from these nucleic acids, for select agent viruses such as including the 1918 influenza virus, ebolavirus and perhaps in the not too distant future, smallpox (Mark Hemphill (CDC), presentation to "Synthetic Genomics Workshop 3," May 31-June 1, 2006, CSIS, Washington DC.). Only when that individual actually makes the virus itself will he or she be in violation of the law.

I do not say this to raise unnecessary alarm. To be sure, generating a virus in this way is far from trivial. The knowledge of how to do so exists for only a few viruses of major bioweapons concern today, and even in those cases it could easily take a skilled postdoc substantial time to achieve success. But for the 1918 influenza virus and ebolavirus, it has already been done. It is not hard to imagine that a skilled terrorist or rogue scientist could work in a government, university or corporate lab, perhaps under cover of a different project, to assemble one of these viruses. No one would be the wiser and, if by chance the individual was discovered, s/he could not be prosecuted unless s/he actually possessed the virus itself. Clearly a careful reconsideration of the Select Agent Rule, or at least of its interpretation by the CDC, is in order.

The OSHA Standards

The third mechanism, addressing biosafety only, is embodied in several OSHA regulations. These are described in more detail in Appendix B. The important point for this discussion is that they are limited to regulating work with certain toxins and work with human blood and other potentially infectious human bodily fluids. Moreover, reporting requirements under these standards apply only when there is a work-related fatality or hospitalization of three or more individuals.

This analysis of the existing US biosafety and biosecurity system shows that it has significant and systemic weaknesses. The system lacks coherence, with multiple different reporting requirements, reporting standards, and agencies to report sometimes similar information to. It lacks clarity about certain critical institutional responsibilities. It lacks transparency and accountability at all levels - reasonable and salient information about the management, operation and oversight of high containment facilities and the US biosafety and biosecurity system that should be public is not public. It lacks universal applicability, leaving gaps in our biosafety and biosecurity web of prevention. The expansion of high containment research and development facilities and dual-use research activities is now stretching that web, rending those gaps ever wider. The time to fix the US biosafety and biosecurity system is now, BEFORE we face any serious consequences of our inaction.

Recommendations

Emerging new risks necessitate corresponding changes in risk mitigation efforts if risk is to be maintained at a steady low level. The United States can rightly be proud that we have often been a world leader in biosafety and biosecurity. From its beginnings in the 1960s to the publication of the NIH Guidelines in 1976, the first edition of the BMBL in 1984, and the first laws governing the handling of bioweapons agents in 1996, the US biosafety and biosecurity system has seen continual improvements in response to demonstrated gaps and emerging risks. It has provided a model for emulation around the world.

We should be continuing this proud tradition. In some ways we are. For instance, the State Department's still expanding Biosecurity Engagement Program (http://www.bepstate.net/) and Sandia National Lab's International Biological Threat Reduction Program (http://www.biosecurity.sandia.gov/) are working closely with other nations to develop systems, practices and "cooperative international programs that promote the safe, secure and responsible use of biological materials that are at risk of accidental release or intentional misuse." ((http://www.bepstate.net/)

Yet, how are these efforts made easier by the problems in our own biosafety and biosecurity system? Can we say that we are truly a leader when it comes to complying with our obligations to under the Biological Weapons Convention and UN Security Council Resolution 1540?

Biological Weapons Convention, Article IV:

> Each State Party to this Convention shall ... take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.
>
> UN Security Council Resolution 1540:
> [A]ll States ... shall adopt and enforce appropriate effective laws which prohibit any non-State actor to manufacture, acquire, possess, develop, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery, in particular for terrorist purposes
> [A]ll States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing appropriate controls over related materials and to this end shall:
> (a) Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport;
> (b) Develop and maintain appropriate effective physical protection measures;

The United States should be a strong and consistent world leader in biosafety and biosecurity, and we should take every reasonable step to ensure the safety and security of our people. Today, the US biosafety and biosecurity system must be made more coherent, more comprehensive, more effective, and more transparent if laboratory workers and the public health are to be adequately safeguarded. Congress and the Federal government can and should take the following actions to help achieve this goal:

Training

Training standards and core competencies. Congress should mandate, and DHHS and USDA should develop, biosafety and biosecurity training standards and minimum core competencies for work with high-risk biological agents, including a plan for meeting national training needs. Agent-specific, BSL-specific and facility-specific (mentored) training should all be required, as should regular refresher training to maintain competence as biosafety and biosecurity needs, practices and facilities evolve. Institutions should be required to keep a detailed record describing the training received by each individual and evidence of competency relevant to the work to be performed. Individual competency should be demonstrated by practical, and not only written, examination prior to being permitted to carry out independent research activities.

Reporting

National Biosafety/Biosecurity Incident Reporting System. Congress should mandate, and DHHS and USDA should develop, operate and maintain a **universally mandatory and transparent** Biosafety/Biosecurity Incident Reporting System (NBIRS). All biosafety and biosecurity incidents (both accidents and near-misses) involving risk group 3 and risk group 4 biological agents, and risk group 2 select agents, would be reportable (See Appendix E for an explanation of risk groups). DHHS and USDA should establish clear reporting criteria and requirements, such as, for example, a requirement that any incident resulting in an occupational exposure as defined by 29 CFR 1910.1030 (See Appendix B) be reported. Other requirements would be to provide specific information on the identify of the agent(s) involved in the incident and an analysis of the cause, effect, and responses taken, in order to enable community-wide learning and safety/security enhancement.

Incident reporting under the NBIRS would be mandatory for all public and private institutions, regardless of whether the conduct classified research. A provision for the withholding of personal, but not of institutional, information could be included for the purpose of guaranteeing individual personal privacy. Similarly, a provision for withholding information while law enforcement authorities are involved in responding to an incident should be included. DHHS and USDA should conduct ongoing monitoring and analysis of the information received, and issue community-wide recommendations for biosafety and biosecurity enhancement as needed. They should issue an annual public report listing the number and categories of incidents by institution and biological agent, and any corrective actions taken. This level of transparency is important for ensuring public accountability and strengthening biosafety and biosecurity practices. It will also provide international reassurance about our bioweapons-related activities.

Finally, institutions should take steps to instill a culture of responsibility, not a culture shame and embarrassment, among researchers. Researchers should know that their responsible behavior will be rewarded, not punished.

State and local notification. Congress should mandate notification of state and local public health and emergency response authorities by the Secretary DHHS or USDA within 12 hours of any accidental or deliberate breach of containment (theft, loss or release, including potential exposure of one or more laboratory personnel, of a biological agent) involving a select agent or a risk group 3 or 4 agent.

Monitoring, oversight and enforcement

Facility licensing and registration. Congress should mandate, and DHHS and USDA should develop, establish and maintain a national licensing system and registry for all BSL-3 and BSL-4 facilities in the

United States, including an integrated and effective auditing process. Criteria and minimum licensing requirements for different general categories of facilities (animal vs. human pathogens, BSL-3 vs. BSL-3Ag vs. BSL-4, etc) should be developed to facilitate the licensing process. Given the wide variations that exist among facilities built at different times for different purposes, a formal public process should be established for issuing any necessary variances. The registry should include information needed for a national inventory of high containment capabilities in the United States in order to facilitate national needs assessments. Information of this type is already collected from institutions applying for registration under the Select Agent Rule, providing a useful model for broader applicability. An integrated and effective auditing process, including a clear and relevant list of key indicators for identifying biosafety and biosecurity deficiencies should be developed. Licensed facilities should be audited regularly (on an annual to triennial basis) to ensure that the minimum required standards for their license category. Evidence of possession of a license should be required with all relevant applications for federal funding.

A national list of all licensed facilities, including a description of their activities, should be publicly available. Any information collected as part of the licensing and registration process which reveals the precise location of select agents, and personal identifying information about individuals who handle them, should remain out of the public eye. General information about which institutions work with which select agents does not pose a significant security risk and should be public. Facilities which conduct classified research should be included on this public national list, but may be allowed to provide more general descriptions of their activities. Current Federal law prohibiting US government agencies from releasing the types of information that would be included in this list should be amended. This level of transparency is important for ensuring public accountability and strengthening biosafety and biosecurity practices. It will also provide international reassurance about our bioweapons-related activities.

The BMBL and NIH Guidelines. Congress should mandate institutional compliance with the BMBL and the NIH Guidelines. Arguments are sometimes made that mandating compliance with the BMBL and the NIH Guidelines would interfere with the individual and institutional flexibility needed to conduct research safely, and that incorporating them into the rulemaking process would make it more difficult to update and revise the recommendations as needed. In recognizing the importance of flexibility and currency for effective biosafety practices, these arguments make an important point. However, they do not consider that the BMBL and the NIH Guidelines contain mainly performance-based recommendations, not hard and fast rules. Mandating compliance with these recommendations and guidelines would simply establish them as performance-based requirements. The OSHA regulation on blood borne pathogens (29 CFR 1910.1030) establishes similar performance-based requirements. It does not impede the adoption of up to date best practices.

Scientists support mandating compliance with the BMBL and the NIH Guidelines. In comments on the Interim Final Select Agent Rule submitted to CDC on February 6, 2003, the American Society for Microbiology advocated that the Rule mandate compliance with the most recent versions of the BMBL and the NIH Guidelines. The ASM is the largest single life science society in the world, with over 43,000 members from a wide range of disciplines. The ASM noted that this "could mandate the state of the art approaches for safety and security." Further, ASM explained that "the CDC will have to update the regulations through rulemaking ... to ensure that when these documents are updated and revised the most current version is incorporated by reference in the regulation." In other words, mandating compliance with these documents would not impede their regular updating and revision. In fact, the ASM noted that mandating compliance with these guidelines would allow "for appropriate updating as the guidelines evolve as the result of research progress." Mandating compliance with the BMBL and the NIH Guidelines is long overdue.

Institutional Biosafety Committee Review. Voluntary compliance with biosafety and biosecurity guidelines is not working. This much is obvious from the discussion in the section above. Congress should mandate Institutional Biosafety Committee (IBC) review of all research projects involving risk group 3 and 4 biological agents, risk group 2 select agents, and other high-risk activities, not just those involving certain categories of rDNA research. This review should consider biosafety, biosecurity, and dual-use issues. DHHS and USDA should develop a standard, performance-based process for such IBC review, and should establish a set of mandatory requirements (training and expertise) for IBC members. As well, they should develop a process for elevating particularly difficult issues, and certain narrowly-defined types of particularly dangerous research, for higher level review. The minutes of IBC meetings should include a work summary and offer sufficient detail to serve as a record of major points of discussion and the committee's rationale for particular decisions.

Responsibility for compliance should be placed at the institutional, not the individual, level. Individual researchers must play a critical role in any review, but the review process should be carried out by an independent body capable of bringing in a wide range of relevant expertise. To ensure universal application of and compliance with these requirements, this mandate should be legally binding on all institutions – government, academic, and private – not just those receiving funds from NIH. This should including all institutions which conduct classified research activities. IBC minutes should be provided to the office described below as evidence that the IBC is complying with these requirements. Public membership on the IBC should continue to be required, as should public access to IBC minutes. Consideration will need to be given as to whether, when and how certain research information, proprietary business information, or national security information should be reasonably protected. Different approaches will likely be required for these different classes of information.

DHHS and USDA should define and fund the development of the training and infrastructure needed to implement such IBC review. The IBC system is in a state of disrepair. In order to effective meet the requirements for IBC review outlined above, the system will either have to be fixed, or replaced. As there is no other system in place which could act as a replacement, and as some institutions appear to have strong and effective IBCs, repairing the IBC system of the preferred option. Funding for this purpose should be provided out of current U.S. biodefense research and development budgets (2% of proposed DHHS and USDA biodefense R&D funding for FY2008 would total $35 million).

> [The NIH Guidelines] have given colleges too much "poetic license." [R]eplacing them with a law would "remove the inconsistencies." ... "People who like to flout guidelines can't flout rules."
> Philip Chandler, Chairman, Medical College of Georgia IBC (Chronicle of Higher Education, April 29, 2005)

Consolidation of monitoring and enforcement. Compliance will be enhanced if regulations are clear, coherent, and integrated. Compliance requires effective monitoring and enforcement – a law not monitored and enforced may be little better than a voluntary guideline. The lack of coherence and integration in the biosafety and biosecurity system, and the administrative, management and likely capacity and capability deficits at in the CDC Select Agent Program and NIH OBA call out for attention. Congress should consider consolidating all CDC and NIH OBA responsibilities and authorities relevant to implementing, monitoring and enforcing the above requirements into a single office located within the Office of the Secretary DHHS. This would help improve coherence in the biosafety and biosecurity system and make it easier for Congress to guide the process of improving monitoring and enforcement of existing and new rules and regulations. At the Secretarial level, DHHS likely has enough distance from the research process that the problems caused by the potentially conflicting objectives of regulation and promotion may be less intense than they are at CDC and NIH. At the same time, DHHS likely possesses and will be able to call on the scientific and institutional knowledge and expertise needed to effectively monitor and enforce biosafety and biosecurity regulations. Absent the consolidation recommended here, Congress will need to find another way to improve coherence, monitoring and enforcement.

Annual report. In order to further strengthen DHHS and USDA implementation, monitoring and enforcement of all of the above requirements, Congress should require that these agencies submit an annual report detailing their efforts in this regard.

Transparency

Amend Section 351A(h). Section 351A(h) of Title III of the Public Health Service Act provides an overly broad exemption for disclosure of certain information pertaining to entities registered under the Select Agent Rules (Appendix C). Moreover, the CDC is interpreting this exemption even more broadly than provided for in the Act (Appendix D). Section 351A(h) is making it easier for institutions and Federal agencies to cover up their mistakes. Meant to strengthen US national security, this Section as currently conceived instead weakens biosafety and biosecurity, and thus national security. It does so by impeding public accountability of institutions and Federal agencies, and by reducing our ability to reassure others that our bioweapons-related research and development activities comply with our obligations under international law. The Section should be amended to more narrowly and accurately define necessary and appropriate requirements for withholding information about activities involving potential bioweapons agents.

Promotion

International promotion. Biosafety, biosecurity and dual-use research are issues of international concern. Congress should mandate that the Executive Branch work to promote the adoption of these strengthened biosafety and biosecurity requirements more broadly by other countries.

Needs and Risk Assessments

Needs assessment for high containment labs. As discussed earlier, no comprehensive interagency needs assessment for determining our high containment laboratory requirements has been performed. Congress should mandate that DHHS, DHS, DOD and USDA conduct a comprehensive interagency assessment to determine current and anticipated US needs for BSL3 and BSL4 facilities. The needs assessment should include, but not be limited to, all information gathered as part of the BSL-3/BSL-4 facility licensing and registration process described above. Congress should further mandate that GAO assess and report on the quality of the interagency needs assessment, including the processes and data used.

Risk Assessments. Congress should mandate, and the GAO should conduct, independent evaluations of safety risks and security risks associated with the recent and continuing increases in the number of institutions and individuals performing bioweapons-related and other high-risk research. Given the widespread concerns that exist in some communities, the assessments should include consideration of siting issues.

Funding moratorium. Congress should impose a moratorium on all future funding for the construction or expansion of BSL-3 and BSL-4 facilities pending completion and review of the above assessments.

Appendix A - Federal Funding for Biological Weapons Prevention and Defense, Fiscal Years 2001 to 2008

Introduction

Since the 2001 terrorist attacks on the United States, the U.S. government has spent or allocated over $40 billion among 11 federal departments and agencies to address the threat of biological weapons. For Fiscal Year 2008 (FY2008), the Bush Administration is proposing an additional $6.77 billion in bioweapons-related spending, approximately $550 million (9%) more than the amount that Congress appropriated for FY2007.[2] U.S. funding for bioweapons-related activities focuses primarily on research, development, and acquisition of medical countermeasures and protective equipment, enhancing medical surveillance and environmental detection of biological weapons agents, and improving state, local, and hospital preparedness. The Department of Defense proposes to double the amount of money that it spends on efforts to prevent the development, acquisition and use of biological weapons by states and terrorists and other non-state actors in FY2008. However, activities aimed at prevention still account for less than 2% of all federal bioweapons-related funding since FY2001. Further strengthening of prevention efforts, including a commitment to broad cooperative international action, are essential for improving our nation's security.

Annual bioweapons-related programs and funding for the following departments and agencies from FY2001 to FY2008 are summarized in Table 1: the Department of Agriculture (USDA), the Department of Commerce, the Department of Defense (DOD), the Department of Energy (DOE), the Department of Health and Human Services (DHHS), the Department of Homeland Security (DHS), the Department of State, the Department of Veterans Affairs (VA), the Environmental Protection Agency (EPA), the National Science Foundation (NSF), and the United States Postal Service (USPS). Table 1 also includes funding for Project BioShield, a ten-year program to acquire medical countermeasures to biological, chemical, radiological and nuclear agents for civilian use. As illustrated in Figure 1, annual bioweapons-related spending grew rapidly from FY2001 to FY2004. Excluding Project BioShield and one-time funding for the US Postal Service in FY2005, federal bioweapons-related funding has remained roughly steady at approximately $6.5 billion/year since FY2004.

Cumulative total funding by agency for the entire FY2001 to FY2008 period ($48.33 billion if the FY2008 request is funded in full) is illustrated in Figure 2, with DHHS funding broken down into its constituent agencies and offices (Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), the Centers for Disease Control (CDC), National Institutes of Health (NIH), and the Office of the Secretary (OS) plus the Agency for Healthcare Research and Quality (AHRQ)). Over 90% of all bioweapons-related funding goes to three lead departments: Health and Human Services, Defense, and Homeland Security (through which Project BioShield is funded).

In contrast to other preparedness efforts, biodefense research, development, testing, and evaluation (RDT&E) can be dual-use in nature: scientific knowledge, methods, and materials that can be used to protect against biological weapons can often also be used to develop biological weapons. The dual-use problem has become a significant national and international policy concern. In the United States, the National Science Advisory Board for Biosecurity (NSABB) has been established under the auspices of

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[2] The estimates presented here differ from those in our FY2007 budget analysis. More refined analysis of Defense Department funding resulted in a reduction of $250 - $300 million annually, due to allocations within the Chemical and Biological Defense Program for chemical and radiological countermeasures. Project BioShield funding was previously reported as annual obligations listed in federal government budget documents. These data are no longer valid given the cancellation of a major BioShield contract, (discussed in Homeland Security analysis section). All Project BioShield funding is now reported in the year that it was appropriated.

Table 1. Federal Funding for Bioweapons Prevention and Defense, by Agency, FY2001 – FY2008 (*in $ millions*)

Department/Agency	**FY01** (actual)	**FY02** (actual)	**FY03** (actual)	**FY04** (actual)	**FY05** (actual)	**FY06** (actual)	**FY07** (estimate)	**FY08** (request)	**FY01-FY08**
Agriculture	7	42	204	111	298	247	187	341	1,437
Commerce	3	4	5	7	6	5	7	7	44
Defense	734	1,046	1,053	1,246	1,335	1,679	1,406	1,690	10,189
Energy	4	5	5	5	5	11	7	5	47
Health and Human Services	324	2,980	4,035	3,704	4,148	4,090	4,044	4,182	27,507
Homeland Security/ Energy legacy	40	85	119	1,038	554	523	397	340	3,096
Project BioShield				885	2469				3,354
State	20	49	35	46	44	37	42	43	316
Veterans Affairs			27	23	9	0	1	0	60
Environmental Protection Agency	20	155	95	114	111	103	103	137	838
National Science Foundation		17	26	27	27	27	28	25	177
US Postal Service	175	587	0	0	503	0	0	0	1,265
Total	**1,327**	**4,970**	**5,604**	**7,206**	**9,509**	**6,722**	**6,222**	**6,770**	**48,330**
Total, excl. BioShield	**1,327**	**4,970**	**5,604**	**6,321**	**7,040**	**6,722**	**6,222**	**6,770**	**44,976**

Figure 1. Total Federal Funding for Bioweapons Prevention and Defense FY2001 - FY2008

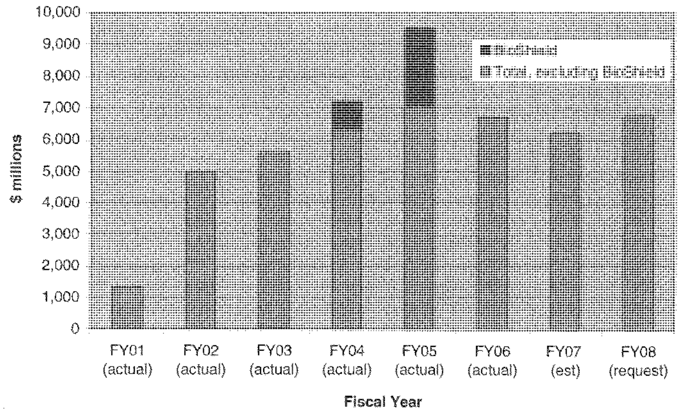
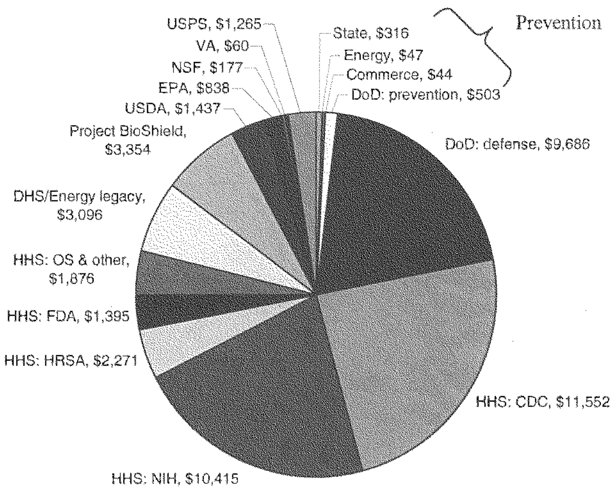


Figure 2. Total Federal Funding for Bioweapons Prevention and Defense by Agency FY2001 – FY2008 *($ millions)*



theNIH, with *ex officio* representation from 18 Federal departments, agencies, and offices, in order to "provide advice, guidance, and leadership regarding biosecurity oversight of dual use research" to the Secretary of DHHS, the Director of the NIH, and the "heads of all federal departments and agencies that conduct or support life science research."[3]

Cumulative funding for biodefense RDT&E from FY2001 through FY2008 will reach $20 billion, over 40% of all bioweapons-related funding since FY2001 (Table 2). Of this, approximately $1.9 billion has thus far been spent, allocated, or requested for improving existing or building at least 20 new high containment research facilities around the country, including 7 new biosafety level 4 (BSL-4) facilities for conducting work on dangerous pathogens such as the ebola viruses and other hemorrhagic fever viruses. The Departments of Defense and Homeland Security are expected to request up to another $1.25 billion over the next five years for two of these BSL-4 facilities.

In contrast, cumulative funding for efforts to prevent the development, acquisition, and use of biological weapons is expected to reach approximately $874 million in FY2008 (Table 3). This is less than 2% of the total funding for biodefense RDT&E during the same time period. FY2008 sees the first substantive increase in funding for prevention efforts since FY2004. If approved by Congress, funding for prevention activities as a percentage of total bioweapons-related funding will increase to 3%, returning it to pre-2001 levels. Approximately 90% of prevention funding goes to the Departments of Defense, Energy and State for Cooperative Threat Reduction efforts, primarily in states of the former Soviet Union. Other prevention-related funding is provided to the Department of Commerce for Export Controls on materials and equipment that could be used to develop biological weapons, and to the Select Agents programs at the

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[3] biosecurityboard.gov

CDC and USDA which regulate the possession, use, and transfer of potential biological weapons pathogens and toxins. The NSABB also receives roughly $1 million per year for its activities.

Table 2. Funding for Biodefense Research, FY2001 – FY2008 *(in $ millions)*

Department/Agency	**FY01** (actual)	**FY02** (actual)	**FY03** (actual)	**FY04** (actual)	**FY05** (actual)	**FY06** (actual)	**FY07** (estimate)	**FY08** (request)	**FY01-FY08**
Facilities									
USDA	7	30	143	0	121	58	0	16	375
DOD						21	29	150	200
DHHS		92	743	0	149	30	25	0	1039
DHS			30	108	68	36	23	n/a[a]	265
Facilities, Subtotal	*7*	*122*	*916*	*108*	*338*	*145*	*77*	*166*	*1879*
Programs									
USDA		9	12	20	29	34	32	81	217
DOD: Army		17	19	22	19	16	25	16	134
DOD: DARPA	146	172	158	142	155	133	113	99	1118
DOD: CDBP	302	488	505	578	565	844	773	827	4882
DOD, Subtotal	*448*	*677*	*682*	*742*	*739*	*993*	*911*	*942*	*6134*
DHHS: FDA	6	46	53	53	57	57	55	57	384
DHHS: CDC	29	20	20	18	17	14	14	0	132
DHHS: NIH	53	198	810	1821	1593	1604	1610	1628	9317
DHHS: OS/BARDA							54	189	243
DHHS, Subtotal	*88*	*264*	*883*	*1892*	*1667*	*1675*	*1733*	*1874*	*10076*
DHS: S&T[b]			53	218	247	244	196	183	1141
DOE	40	85							
VA	n/a	n/a	27	23	9	0	1	0	60
EPA: S&T	0	5	17	33	51	46	46	67	265
NSF	0	17	26	27	27	27	28	25	177
Programs, Subtotal	*576*	*1057*	*1700*	*2955*	*2769*	*3025*	*2947*	*3172*	*18201*
Research, Total	***583***	***1179***	***2616***	***3063***	***3107***	***3170***	***3024***	***3338***	***20080***

[a] n/a: no information available.

[b] Based on estimate that 60% of non-facility Biological and Chemical Division funding from FY2003 - FY2007, and 80% in FY2008, is devoted to biodefense RDT&E.

Table 3. Funding for Bioweapons Prevention Activities, FY2001 – FY2008 *(in $ millions)*

Department/Agency	**FY01** (actual)	**FY02** (actual)	**FY03** (actual)	**FY04** (actual)	**FY05** (actual)	**FY06** (actual)	**FY07** (estimate)	**FY08** (request)	**FY01-FY08**
USDA:APHIS: Select Agents					3	3	3	7	16
DOD: CTR	12	17	55	68	69	70	68	144	503
DHHS: CDC: Select Agents[a]	5	5	5	5	5	5	5	5	40
State: Nonproliferation Programs	16	45	20	29	27	25	31	32	225
Commerce: Export Controls	3	4	5	7	6	5	7	7	44
DOE: NIS Programs	4	5	5	5	5	5	7	5	41
Prevention, Total	**40**	**76**	**90**	**115**	**116**	**114**	**122**	**201**	**874**

[a] HHS and CDC do not provide data on funding for the Select Agent Program. This is an estimate based on USDA data and CDC data from FY2002 (from GAO-03-315R "CDC Select Agent Program," 11/22/02).

The NIH Guidelines

The first mechanism, which addresses biosafety only, is the system established by the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines). The NIH Guidelines apply to all institutions that receive funding from NIH and conduct research involving recombinant DNA (rDNA). Such institutions are responsible for ensuring that all research covered by the Guidelines is conducted in accordance with the provisions of the Guidelines (Section IV-B-1). Among their responsibilities, they must establish an Institutional Biosafety Committee (IBC) and file an annual report listing the names and biographies of all IBC members with the NIH Office of Biotechnology Activities (OBA) (at present, approximately 400 IBCs are so registered with OBA). Institutions must also appoint a Biological Safety Officer (BSO) if they conduct rDNA research at BSL-3 or BSL-4. They must "ensure appropriate training" for the IBC Chair, the BSO, and all relevant personnel regarding biosafety and implementation of the Guidelines, and they must establish a health surveillance program if they conduct rDNA research at BSL-3 or higher. Investigators must subject all research involving rDNA to a risk assessment in order to determine the appropriate containment level for their work (Section II-A). The Guidelines provide recommendations to facilitate this process, including the categorization of biological agents into one of four "risk groups." (Section II and Appendix B). The IBC must provide independent prior review and approval for certain rDNA research (defined in Sections III-A to III-D). To enhance transparency and public accountability, institutions are required to provide public access to IBC meeting minutes, which "should offer sufficient detail to serve as a record of major points of discussion and the committee's rationale for particular decision." (Section IV-B-2). Finally, institutions or their IBCs must report any "significant problems [or] violations" of the NIH Guidelines, and any "significant research related accidents or illnesses" involving rDNA, to OBA within 30 days (Section IV). Spills or accidents that result in "overt" exposure at BSL-2, or "overt or potential exposure" at BSL-3 and BSL-4 must be reported immediately (Appendix G). Failure of an institution to comply with the Guidelines can result penalties up to and including the termination of NIH funding of research involving rDNA at the institution (Section I-D).

There are a few absolute prescriptions in the NIH Guidelines. For instance, any experiments involving the introduction of rDNA into Risk Group 4 agents must be conducted at BSL-4. Experiments in which DNA from such agents is transferred into other microorganisms may be performed at BSL-2, but only after it has been demonstrated that "only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant." In the absence of such a demonstration, the work must be performed at BSL-4. Finally, containment conditions for all experiments involving the transfer of DNA from the smallpox virus into other microorganisms must be determined by OBA following a case-by-case review (Section III-D). In addition, two specific types of research require approval by the NIH Recombinant DNA Advisory Committee (RAC) and/or the NIH or another federal agency with jurisdiction for review and approval (Sections I-A, III-A, III-B). These are any experiments involving the cloning of genes coding for toxin molecules having a median lethal dose of less than 100 nanograms per kilogram body weight, and any experiments involving the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally "if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture." (There are also requirements for review and approval of human gene therapy experiments, but these are not discussed further here). Experiments involving the cloning of less potent toxin genes must be registered with OBA prior to their initiation (Appendix F).

The Select Agent Rules

The second mechanism, addressing both biosafety and biosecurity, is provided by the Select Agent Rules promulgated by APHIS and the CDC under the Public Health Security and

Bioterrorism Preparedness and Response Act of 2002. This discussion is based on the Rule promulgated by CDC (at 42 CFR 73). The Select Agent Rules define a list of "select" biological agents, toxins and genetic materials that "have the potential to pose a severe threat to public health and safety, to animal health, or to animal products" and provide for the registration and oversight by the federal government of all entities in the United States who posses, use or transfer such agents, with certain exemptions. The possession, use or transfer of a select agent without a certificate of registration is illegal under federal law. As outlined in Section 73.7, to obtain a certificate of registration an entity must designate a Responsible Official (RO), and both the entity and RO must undergo a security risk assessment by the Justice Department. Certificates of registration are valid only for specific physical locations, specific select agents or toxins, and specific activities. Registered entities may not provide an individual with access to a select agent or toxin unless the individual receives access approval from the federal government following a security risk assessment.

The Rules specify that a registered entity must maintain a complete inventory of all select agents and toxins, including their names, characteristics, storage locations, dates accessed, and uses (42 CFR 73.17). The entity must adhere to specific security requirements "or implement measures to achieve an equivalent or greater level of security," and must develop and implement a written security plan which includes certain specified types of information and is "sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss or release." (42 CFR 73.11). The entity must also develop and implement a written biosafety plan that is "commensurate with the risk of the agent or toxin, given its intended use." The plan "must contain sufficient information and documentation to describe the biosafety and containment procedures," which "must be sufficient to contain the select agent or toxin." In developing the plan, the entity "should consider" the BMBL, the NIH Guidelines, and the OSHA regulations at 29 CFR 1910.1200 and 1910.1450 (see more below)(42 CFR 73.12). The entity must also develop and implement a written incident response plan which fully describes the response procedures in case of theft, loss or release of a select agent or toxin and contains certain basic emergency response information (42 CFR 73.14). Each of these plans must be reviewed, evaluated and revised as necessary on an annual basis.

Each individual with access to select agents and toxins "must have the appropriate education, training, and/or experience to handle or use such agents or toxins." (42 CRF 73.10(c)). The registered entity must "provide information and training on biosafety and security to each individual with access approval ... before he/she has such access," and must also provide information and training on biosafety and security to each individual not approved for access before he/she works in or visits areas where select agents or toxins are handled or stored. The training "must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins," and refresher training must be provided annually. A record of such training, including the date of the training, a description of the training, and the means used to verify that the individual understood the training, must be maintained. (42 CFR 73.15).

The entity must obtain prior federal approval before conducting any experiment with a select agent or toxin that involves the deliberate formation of rDNA containing genes for toxins having a median lethal dose of less than 100 nanograms per kilogram body weight, or the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally "if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture." (42 CFR 73.13)

The entity must immediately notify the CDC and other appropriate Federal, State or local authorities upon discovery of the theft or loss of a select agent or toxin. It must immediately notify the CDC upon discovery of a "release of an agent or toxin causing occupational exposure or the release of a select agent or toxin outside the primary barriers of the biocontainment area. In each case, written notice must also be filed within seven days. (42 CFR 73.19).

Finally, when applying for a certificate of registration, an entity must submit a CDC Form 1. The Form must include information on the biosafety level at which the specific registered activity will be conducted. The biosafety level "should" be determined by a biosafety risk assessment that "should" be based on the requirements at 29 CFR 1910.1450, the BMBL, and the NIH Guidelines. The RO must certify that the entity is capable of safely and securely handling the agents or toxins specified in the application, and that "information and training on safety and security for working with select agents and toxins" has been provided to each individual for whom access approval is requested. Certain other biosafety and security-related information must also be provided. The issuance of the certificate may be contingent upon inspection of the entity or the submission of additional information including a security plan, biosafety plan, incident response plan, or any other required documents (42 CRF 73.7(f)).

The third mechanism, addressing biosafety only, is embodied in several OSHA regulations. In 1992, OSHA established a legally binding standard for working with bloodborne pathogens (29 CFR 1910.1030). The standard requires the employers establish and regularly update and maintain a detailed written Exposure Control Plan designed to eliminate or minimize employee exposure to human blood or other human bodily fluids, tissues or organs that may contain infectious materials. It defines "occupational exposure" as "reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties." The standard includes detailed requirements for engineering and work practice controls, personal protective equipment, waste management and disposal, employee training, and record-keeping. Similarly, OSHA has established a legally binding standard for work with hazardous chemicals, including certain toxins (29 CFR 1910.1450). Finally, OSHA requires that employers with 10 or more employees must record and report work-related fatalities and illnesses. Further, any fatality and any hospitalization of three or more individuals which occurs within 30 days of and is due to a work-related incident must be orally reported to OSHA within 8 hours (29 CFR 1904).

Appendix C - Section 351A(h) of the Public Health Service Act

As added by Title II of the Bioterrorism and Public Health Emergency Preparedness and Response Act of 2002

(h) Disclosure of Information.--

``(1) Nondisclosure of certain information.--No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5, United States Code, any of the following:

``(A) Any registration or transfer documentation submitted under subsections (b) and (c) for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or by a specific registered person or discloses the identity or location of a specific registered person.

``(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b) and (c) to the extent that such compilation discloses site-specific registration or transfer information.

``(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

``(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any notification of theft or loss submitted under such subsections.

``(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

``(2) Covered agencies.--For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

``(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

``(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

``(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

``(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

``(3) Other exemptions.--This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, United States Code, except as to subsection 552(b)(3) of such title, to any of the information specified in paragraph (1).

``(4) Rule of construction.--Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, United States Code, or the obligation of any Federal agency to disclose under section 552 of title 5, United States Code, any information, including information relating to--

``(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

``(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

``(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c); or

``(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

``(5) Disclosures to congress; other disclosures.--This subsection may not be construed as providing any authority--

``(A) to withhold information from the Congress or any committee or subcommittee thereof; or

``(B) to withhold information from any person under any other Federal law or treaty.

Appendix E - Primer on Pathogen Risk Groups

The NIH Guidelines establish an agent risk group classification scheme that describes four general risk groups based on the infectivity and pathogenicity (ability to cause disease) of a biological agent, its virulence (severity of disease), the availability of preventive measures and effective treatments for the disease, and the route of transmission of the natural disease. The four groups address the risk to both the laboratory worker and the community. Risk groups correlate with but do not equate to biosafety levels (BSLs). A risk assessment is used to determine the appropriate BSL at which to conduct work with a pathogenic agent. The risk assessment is based on the risk group of the agent, its mode of transmission, procedural protocols, experience of staff, and other factors.

Risk Group 1
Agents that are not associated with disease in healthy adult humans.

Risk Group 2
Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available. Examples: anthrax, salmonella, dengue, measles)

Risk Group 3
Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk). Examples: plague, tularemia, tuberculosis, hantaviruses, HIV

Risk Group 4
Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high community risk).
(High individual and community risk) Examples: ebola, Marburg,

Mr. STUPAK. Thank you. Mr. Hammond, opening statement, 5 minutes, sir.

STATEMENT OF EDWARD HAMMOND, THE SUNSHINE PROJECT

Mr. HAMMOND. Thank you, Mr. Chairman. It is the Sunshine Project and to explain what it is, it is a very small, non-governmental organization. We are based in Texas in the U.S. and Austin and also have an office in Hamburg, Germany and we are dedicated to biological weapons control.

I have submitted lengthy written comments and addressing many of the issues that the prior panelists have addressed. I am not going to go back over them but I have presented some additional thoughts about where Congress might go on some these issues that have been raised. So to minimize duplication, I really just want to highlight a few of the things that I brought up in my written comments.

The first thing that I would like to do is just to give a little bit of shape and talk a little bit about some data on the lab expansion that my organization has put together with Margaret Race from the SETI Institute. If you look at page two and three of my written testimony, we have tried to bring together a table that has data on the most important new labs that exists or are under construction. This table excludes a lot of laboratories that we know of. But if you look at just those labs that are there, you are talking about a construction spree that is going on right now that is approximately 4 million gross square feet. That is 90 acres of laboratory space that is either under construction or is going to be under construction shortly. In terms of BSL–4 space, the historic amount, in fact, the amount up until mid–2004 in the United States was about 14,000 net square feet. With the projects that are on the books right now, we are looking at approximately 165,000 square feet just with what is already either under construction or planned. That is a 12-fold increase approximately. We do not know the final finished square footage of some of the labs that are under construction but that is the best estimate that we can make. The four million square feet, to put that in terms that I think are more readily understandable, that is the size of about 36 big box stores. That is how much lab space we are going—if you stretch them end to end, it would a chain that is 2¼ miles long.

The second issue that I want to bring up which has not been directly addressed is that of transparency of the Centers for Disease Control. I filed numerous Freedom of Information Act requests with the Centers for Disease Control, spoken to many journalists and other non-governmental organizations that have done the same. It is the apparent policy of the Centers for Disease Control to not even attempt to locate records regarding select agents. They deny absolutely all requests for anything. So the level of transparency with respect to the Centers for Disease Control on its oversight of select agents is, well, non-existent. There is none. And I think that if I lived near a biological facility I would frankly find that to be offensive.

Moving on, and I think this is an important point because it is emerging now, I believe that there is a positive correlation between the transparency of these laboratories and compliance and accident reporting. We saw in the case of Texas A&M that the revelation of one accident caused them to report several additional reportable incidents that occurred at the university. In my own research since then, I have found that two other institutions in Texas have reported select agent accidents, both of which occurred after Texas A&M became public. Those institutions did not report anything prior. And if the data that is coming out in the press now and the Associated Press and in other sources in the last few days is correct, there has been a tremendous spike in reports to the Centers for Disease Control of accidents involving select agents since April 2007. And I believe that that spike is, at least in part, attributable to—first of all, it is attributable to the expansion of our laboratories to begin with. But second of all, it is attributable to the transparency at Texas A&M. So there is a positive correlation between the two.

Finally, to wrap up, with respect to the expansion of laboratories, I believe that our country does not need 400 laboratories and 15,000 people handling biological weapons agents. Our system cannot absorb all the new laboratories that are coming on line. Even with explicit training, we still do not need 400 laboratories and 15,000 people handling biological weapons agents. We do not have the people to absorb a 12-fold increase in biosafety level 4 capacity. I believe that Congress should act to impose a moratorium. It should not authorize construction of any new biodefense facilities and it should consider killing some projects that are underway. Among those, the National Bio and Agro-Defense Facility, the very unpopular lab at Boston University and the Regional Biocontainment lab at Hawaii, which is late and over budget. Even if we kill those projects, we are still going to be increasing our biosafety level 4 space by approximately seven-fold. And we should do that and step back and perform the national needs assessment and then we can move forward if we need to move forward with any new labs. Thank you.

[The prepared statement of Mr. Hammond follows:]

WRITTEN TESTIMONY OF EDWARD HAMMOND

Director, The Sunshine Project, Austin TX

Submitted to the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce for the Hearing: *Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States*, 4 October 2007.

PROLIFERATION OF LABORATORIES HANDLING BIOLOGICAL WEAPONS AGENTS

There has been a large and unsafe expansion of US laboratories handling biological weapons agents since 2002. This expansion poses significant risks to the public through accidents and incidents of domestic source criminality (bioterrorism). Inadequate transparency exacerbates risks to the public and threatens international confidence in the objectives and activities of this US research, damaging prospects of improving global biosecurity.

The unprecedented expansion of biological weapons agent research has been conducted without a national laboratory needs assessment and appears to far exceed that which is prudent and necessary for our national needs.

The Sunshine Project has tracked the proliferation of high containment laboratories since 2002. The media and the public regularly ask me where the federal government publishes this information. It does not. There is no comprehensive government source of information available on where these labs are and are being built. In fact, the Sunshine Project's data on lab proliferation has been requested by government agencies for their use and frequently appears in the news media.

The following data on many of the most important labs, including all known US biosafety level four facilities, has recently been prepared by the Sunshine Project and Margaret Race of the SETI Institute:

Table 1: US Operational BSL-4 Lab Space as of May 2004

Facility	BSL-4 sq.ft	Comments
Ctr. For Disease Control and Prevention (CDC) Atlanta, GA	3630	Since 1970's; 2 BSL-4 suites; info from Gronvall et al 2007.
USAMRIID Ft. Detrick, MD	8640	Operational since 1969; No details avail. on additional BSL-3/2 capacity; Info from Miller (2005)
Southwest Foundation for Biomedical Research (SFBR) San Antonio, TX	1200	Operating since 1999, the only US privately owned BSL-4 (1200sf), with ABSL-4 space; BSL-3(+) (2100 sf); BSL-2 (10,000sf). Had small glovebox BSL-4 since the 1970's. Also site of Southwest National Primate Res. Ctr. on 450 acres with ~4600 primates. (www.cbwtransparency.org/archive/regvircecores.pdf).
Georgia State U. Atlanta,GA	700	Hilliard Lab, BSL-4 glovebox line; Herpes B only (Hedetneimi, J. & E. Gaunt 2005)
Total US Operational BSL-4	**14,170 sf**	Earlier estimate ~15,500sf [2]

Table 2: Planned and Under Construction New BSL-4 and Other Biodefense Labs, September 2007

Facility	BSL-4 sq.ft	BSL-3 sf	BSL-2 sf	Total GSF	Cost $M	Comments
NBLs*						* Data on NBLs from NIH-EIS documents
Boston Univ. Medical Ctr.	13,100	10,900	17,700	194,000	178	Plus 15,400 sf of animal holding/support space assoc. w/ BSL-3 and BSL-4 labs
UTMB	12,362	18,223	16368	82,411	167	BSL-4(6,488sf) & ABSL-4(5,874sf); ABSL-3 (8964sf) & ABSL-3 labs (8,380sf) & BSL-3 insectary (879sf); BSL-2 (16,368sf)
OTHER BSL-4**						**Excludes "surge" BSL-4 at Biotech Six (Richmond, VA), NIH Building 41A (Bethesda MD) and NIH Twinbrook (Rockville MD).
NIH-NIAID IRF at Ft Detrick	~20,000	(yes)	(yes)	~148,000	Estimated $1.2B for National Interagency Biodefense Campus at Ft. Detrick (combined DOD, USDA, NIAID)	To be completed early 2008; Construction budget $105 million. Information from Miller (2005)(BSL-4~ 20,000sf) and www.detrick.army.mil/nibc.nibc02.cfm.
DHS-NBACC Ft. Detrick	~9,000	~9,500	(yes)	160,000		National Biodefense Analysis & Countermeasures Center 160,000 gsf of BSL-4, BSL-3 and BSL-2 labs and administrative space to be completed in June 2008. Estimated construction cost: $141 million
USAMRIID Ft. Detrick (proposed)	27,531	647,469 BSL-2/3 (675,000 sf total BSL-4/3/2 space)		700,000 + 400,000		To be built in 2 phases (for 900+400 workers). BSL-4 upgrades = $6M. Info from Fed.Reg. 8 Feb 06, v 71(26), p 6456-57); and www.detrick.army.mil/nibc.nibc02.cfm
USDA, Ft. Detrick (FDWSRU)	0	~7500	~2500	?		Foreign Disease-Weed Science Research Unit. Currently has 7500sf of BSL-3+ (Enhanced greenhouses w/ shower-out) plus 2500 sf of other labs. Plan to update BSL-3 plant pathogen labs (www.detrick.army.mil/nibc.nibc02.cfm)
CDC Atlanta (New EID facility)	~10,000	(yes)	(yes)		214	4 BSL-4 suites (no details avail on other parts of the lab); Info from [9,2]
DHS-USDA NBAF Location TBD	~50,000	(yes)	(yes)	500,000	$451	$23M for design (with BSL-3, BSL-3Ag, BSL-4) (Fed.Reg. 19Jan06, v 71(12), p3107-09) Estimated cost $451Mil., >400 plus new jobs; to be located on over 30 acres) Per DHS NEPA EIS Scoping Meeting (8/07), facility will be approximately 10% BSL-4 (pers. comm. Alan Pearson)
NIH- RML IRF Hamilton MT	6760	2,950	14,650	105,132	67	info from NIH-RML IRF EIS (2004); Completion set for 2007
U Texas Medical Branch Shope Lab, Galveston, TX	2100	7600	(yes)	~10,000	~$25	Became operational in June 2004. BSL-4 (1200 sf on one floor in a stand alone 3-story bldg with 10,000 total sf.), 8 BSL-3 labs (5200 sf) & ABSL-3 (2400sf); Adjacent Keiller Bldg contains 102,000 GSF with 38 BSL-2 and 9 BSL-3 labs. (info from UTMB EIS (2005) and www.cbwtransparency.org/archive/regvircecores.pdf
RBLs***						** Data on RBLs from NIH Environmental Assessment Rpts. or NIH CRISP system
Tulane U.	0	16,730		39,800	19	21,012 sf comprised of ABSL-3(6679sf), BSL-3 (2379sf) plus BSL-3 wash(7673), plus adm area (4192sf); Bldg footprint 23,322 sf; Mechanical area (16,480sf)
Duke U (GHRB)	0	17,000		24,000	16	Combined BSL-2 and BSL-3 (no breakdown of sq ft avail)
U Louisville	0	(yes)	(yes)	37,000	34.6	
U. Chicago (HTRL) at DOE Argonne Nat. Lab.	0	27,541		54,100	32	Max. footprint 44,000sf. Includes: BSL-2 and BSL-3 molec lab (8900 sf), plus BSL-2 and BSL-3 animal research labs (13,300 sf) (with vivarium w/ holding capacity for 30,000 mice or experimental animals) note: BSL-2 and -3 combined (no detail available)
Colorado State U. RBL, at Ft. Collins	0	23,710		39,250	22	5 BSL-3 suites + ABSL-3 area with aerosol capacity; plus BSL-2 labs (no breakdown of sq ft avail) (Already at Colorado: 3 BSL-3 suites (12687 GSF)
U Pittsburgh RBL	0	18,000		~32,000	18+	4 ABSL-3 suites, 3 BSL3 suites, 2 BSL-2 labs (note: BSL-2 and BSL-3 combined; no detail provided). On one floor in a 10 story, 326,000 GSF bldg.
U Alabama (SEBLAB) Birmingham	0	18,000		41,060	21	BSL-2 and BSL-3 plus ABSL-3 housing and procedure space
U Missouri,	0	9,796		35,000	6.8+	BSL 2/3 combined; no breakdown of sq ft avail.

Col. Vet Med, Columbia						
RBL Newark Center	0	13,480	4,250	17,730	21+	at College of Medicine/Dentistry, NJ
U Tennessee HSC Memphis	0	6,381	1,297	31,000	25	Federal portion: $17.7m.
Tufts U (Grafton, MA)	0	8,480	649	37,950	25.8	Federal portion: $19.35m
U Hawaii - Manoa	0	(yes)	(yes)	38,403	37.5	$25 million is federal portion of cost. Wildly varying size and cost numbers published. Numbers from UH website at left, NIH .CRISP database says 70,000 ft2 building.
George Mason Univ	0	(yes)	(yes)	83,154	42	$25 million is federal portion of cost.
OTHER BSL-3s****						***** Selected facilities. More are planned or have been constructed, e.g. at Dugway Proving Ground, UT and ECBC Edgewood, MD**
DHS-USDA Plum Island (PIADC) (existing)		Enhance existing facility & new 8000 sf animal wing & 2500sf BSL-3 labs		~164,000	~30	BSL-3, BSL3Ag, + 32 animal isolation rms @10x15 ft each (Carroll, 2004); upgrade/expand Animal wing (+8000 sf) plus 2500 sf BSL-3 lab and other upgrades (DHS/USDA solicitation LGL0600012, Improvements at PIADC, 23 June 06)
CDC Vector-Borne Infec. Disease Lab Ft. Collins, CO		(yes)	(yes)	156,000	$104.5+	Replaces 31,000 sf building (fate of old lab unreported). (*Ft. Collins Coloradoan*, 17 June 2005) (HHS Budget in Brief, Fiscal Year 2006)
Lawrence Livermore Natl Laboratories (LLNL-DOE)		1500			1.5M	Three BSL-3 lab rooms in a one story permanent prefabricated facility with mechanical room, clothes-change and shower rooms, and small storage space (DOE Environmental Assessment 2002)
Los Alamos Natl. Lab. (LANL-DOE)		800		3,000	?	Lab has not commenced operations pending outcome of litigation filed by watchdog organizations. (DOE Environmental Assessment 2002)
USDA ARS Hi Containment. Large Animal Fac.(Ames IA)		52,000		140,224	~100M	To be completed in 2007. Large BSL-3AG area is to house "cattle, bison, elk, deer, reindeer, sheep, and hogs". (USDA National Animal Disease Ctr: Modernization, URL: http://www.ars.usda.gov/Main/docs.htm?docid=10858)
USDA ARS / APHIS Natl Ctr for Animal Health Phase II (Ames, IA)		(yes)	(yes)	545,803	>200M	Groundbreaking Sept. 2005.Anticipated Opening: October 2007. Funded in multiple years and multiple line items. No figure on total cost or total BSL-3 square footage is available, although likely quite large. (USDA National Animal Disease Center: Modernization, see URL above)
USDA APHIS Nat'l Wildlife Research Center (Fort Collins, CO)		750 sf of BSL-3 in animal wing, plus 15-20,000 sf of labs in new building, including BSL-3		33,500	?	750 sf of BSL-3 added to new 8,500 sf Animal Support Wing in 2004. A new 25,000sf research building, to be completed in 2008/09, includes 15-20,000 new sf of lab space, including BSL-3. (USDA APHIS Wildlife Services. "Expanding Research Capabilities Through New Construction", 2006)
Kansas State University Biosecurity Res. Institute; Manhattan KS		~31,000 sf		113,000	$54	Research & Training related to food safety and security—with biocontainment for food crop and animal infectious disease research and a biosecurity education & training suite. Includes 10,000 sf admin area. http://www.mediarelations.k-state.edu/WEB/News/Webzine/safetyandsecurity/BRI.html, Oct. 2006) (accessed 7/24/07)
TOTAL	**165,000+ sq. ft.**			**> 3.9Million GSF**	**>$ 3.1 Billion**	

The incomplete list of new labs reflected in this data together constitute nearly 4 million gross square feet of new facilities, about 90 acres of space. In perhaps a more recognizable measure, this is the equivalent of 36 typical "big box" stores for the study of biological weapons and other dangerous agents. Placed end to end with no space between, the row of stores would stretch 2 ¼ miles.[1] These figures do not include many dozens of new and converted BSL-3 facilities at other public and private research institutions.

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[1] A Wal Mart store, for instance, averages 107,000 square feet (as of August 2007), the equivalent of a square 327 feet per side. (End to end: 327' x 36 stores = 11,772 feet, or 2.23 miles.)

For BSL-4 laboratories in particular, the historical square footage in the United States has been slightly over 14,000 net square feet. The total US finished square footage of US BSL-4 labs will grow to over 165,000 net square feet (3.79 acres) when presently planned and under construction facilities are completed. This is a twelve-fold increase.

Because no one knows how many BSL-3 labs there are in the US and where they are all located, as well as gaps in public information on new federally-funded facilities to study biological weapons agents, it is not possible to calculate the corresponding increase in BSL-3 capacity, however, it is plainly very large. The National Institutes of Health has funded 13 new Regional Biocontainment Laboratories, plus its own new facilities and others constructed by government agencies including the Departments of Defense, Energy, and Agriculture. In addition, many universities and other institutes have constructed BSL-3 and even BSL-4 labs with their own funds, seeking to use the existence of the facility as leverage for federal research funding.

It is important to note that while BSL-4 labs are most frequently in the public eye because they are purpose-built to handle the most dangerous biological agents, BSL-3 laboratories handle diseases that are also extremely dangerous to both researchers and the public and which even pose potentially catastrophic risks if released by accident or malfeasance. These include diseases capable of transmission through the general population such as pandemic strains of influenza such as 1918 "Spanish" Flu, SARS coronavirus, and plague (*Yersinia pestis*) as well as animal and/or human threats such as Foot and Mouth Disease and H5N1 "Bird Flu" strains.

NEED FOR A TRANSPARENT AND ACCOUNTABLE BIODEFENSE PROGRAM

As evidenced by the offensive biological weapons activities of the Soviet Union in its waning years as well as those of Iraq prior to the First Gulf War, the United States needs a biological defense program. In addition, the rate of discovery in biotechnology fields including genetic engineering and synthetic biology and the proliferation of associated knowledge merit assessment of by a biodefense program, strictly and always in ways permitted by the Biological and Toxin Weapons Convention. For those reasons and following the events of 2001, an expansion of the US biodefense program was merited and this expansion would logically include new and/or upgraded laboratory facilities commensurate with an increased effort.

In the past 6 years, however, lab expansion under the Bush administration has gone far beyond what is prudent and necessary, and without an adequate regulatory framework. According to the most recent statements by the Centers for Disease Control, there are now approximately 400 facilities and 15,000 people in the United States handling biological weapons agents. Many of these facilities are new and are staffed by scientists and others with little to no prior experience with biological weapons agents and the safety and security measures they require. In addition they are frequently on college campuses and other locations where rule-based systems of strict accountability are absent and, in fact, alien to institutional culture. It is plain to see that our own scores of laboratories that study biological weapons agents represent the easiest avenue by which a would-be bioterrorist could obtain the materials and knowledge necessary to commit crime in the United States.

Thus, a reduction in the number of facilities and persons handling biological weapons agents is a highly desirable step for both safety and security. This could include cancellation or conversion of some planned and under construction facilities and rerouting of some appropriations toward basic research and public health, to help address the health problems that Americans most frequently face, which are not at all typically caused by biological weapons agents.

Research with biological weapons agents must be transparent and publicly accountable. A culture of transparency does not presently exist. Laboratories would be more likely to conduct research in a prudent and safe manner with the public able to look over their shoulder. Access to records such as research protocols, safety minutes, and accident reports will help ensure that studies are conducted with public safety and security in mind and, most importantly, reassure other countries of the peaceful intent and activities of the US biodefense program.

While laboratories frequently raise security concerns in relation to release of records, having filed more than 1,000 requests for such information it is the Sunshine Project's experience that is possible to easily satisfy these concerns by redaction of information pertaining to the immediate physical security of biological weapons agents, such as room numbers and details of security systems. Redaction of this small amount of information, which is not even present at all in many records, affords the public access to information without compromising physical security. Regrettably, many public institutions continue to redact far more than what is necessary while at many private labs there is no access to records under any open records law.

In addition to making us safer from accidents and deliberate acts emanating from our own labs, transparency signals to the world the peaceful intent of US research and lessens the likelihood that other countries will pursue secretive research with biological weapons agents. Transparency will thus reduce the chance of an international "biodefense race" and improve prospects for the Biological and Toxin Weapons Convention to be strengthened.

Since 2001, the Sunshine Project has studied the proliferation of labs handling biological weapons agents. Under the following and subsequent headings, the Project's most important findings are presented.

INABILITY TO TRACK FEDERALLY FUNDED BIOLOGICAL WEAPONS AGENT RESEARCH AND VERIFY PROPER LOCAL OVERSIGHT

Our research indicates that in the vast majority of cases, it is not possible to verify that federally funded research is properly overseen at the local level, nor are the local committees that are charged with overseeing this research actually required to produce meeting minutes or annual reports that demonstrate that they have fulfilled this charge.

In 2006, the Sunshine Project surveyed all institutions with Institutional Biosafety Committees (IBCs) registered with the National Institutes of Health. IBCs are local committees operating under the NIH Guidelines for Research Involving Recombinant DNA Molecules. By grant contract, IBCs are mandatory for institutions receiving NIH funding involving recombinant DNA (genetic engineering) and for certain other labs by departmental rule or regulation. It is also federal policy that IBCs review not only genetic engineering projects; but also those involving biological weapons agents.

Here it should be initially noted that there is a misconnection between the historical purpose and non-legally binding nature of IBC system, set up for rDNA funding from NIH, and the task of local oversight of research involving biological weapons agents, which might or might not occur at an institution funded by NIH and might or might not involve genetic engineering. (This issue is discussed further later in this testimony.)

The survey asked for the last three years of meeting minutes from each IBC. The meeting minutes must be made available to the public under the Guidelines.[2] From the responses, a subsample of 100 institutions was identified that have BSL-3 or higher containment. The minutes of these institutions were assessed to identify review of research projects requiring BSL-3 containment.[3] This information was then correlated against public data on government research grants, specifically, NIH CRISP, USDA CRIS, and the Rand Corporation Radius databases, where grants to the institution that appeared to require BSL-3 or higher containment were identified.

Table 3: Low Level of Correlation Between Grant Databases and IBC Review[4]

Category	% of Institutions (n=100)
Category 1. IBC minutes reflect review of all identifiable federal grants requiring BSL-3 (correlation = 1.0 between database and IBC information)	2%
Category 2: IBC minutes reflect review of most such grants (correlation .5 to .99)	11%
Category 3: IBC minutes reflect review of less than half such grants (correlation = .01 - .49)	28%
Category 4: Institutions that have received federal grants for research requiring BSL-3; but whose IBC minutes do not reflect review of any of those grants. (correlation = 0)	27%
Category 5: Institutions that have BSL-3 containment; but no federal grants in CRISP, CRIS, or Radius that appear to require BSL-3 containment	32%

The result is that local IBC oversight could only be verified for all relevant federal grants in 2 out of 100 cases (2%). This means it was impossible to fully correlate federal grants and IBC reviews in 98% of the identified BSL-3 labs. In 11 cases (11%), IBCs reviewed most federal grants requiring BSL-3 containment. The majority of respondents (55) had matches of less than half their research (28 IBCs) or none at all (27 IBCs).

In this analysis, there were repeated instances of biological weapons agent research found in minutes that could not be correlated with a federal grant. Such research involved a range of organisms including anthrax, monkeypox, highly pathogenic avian influenza, plague, brucella, melioidosis, eastern equine encephalitis, and others. Due to a lack of grant information and/or inadequate minutes, in some other labs it was impossible to discern what research, if any, is taking place. This may be attributable to underreporting by the federal government of grants

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[2] "Section IV-B-2-a-(7). Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public."

[3] Here institutions with BSL-3 containment that appears to be used solely with HIV (AIDS virus) were excluded.

[4] Development and presentation of data in this and other tables has been in collaboration with Margaret Race of the SETI Institute.

(e.g., there is a paucity of information on DOD and DHS grants) or it could be that institutions are initiating biological weapons agent work with alternative, non-federal sources of funding.

Nearly one third (32%) of the institutions identified had no federal grants in CRISP, CRIS, or Radius that appear to require BSL-3 containment. What is happening in these facilities, if anything, cannot be determined from the on the basis of available information on federal grants.

The minutes were also assessed to determine if institutions are following federal advice to use their IBCs to review both biohazard and recombinant DNA research. In addition, adherence to NIH advice about disclosure in IBC minutes was assessed, with a result indicating that institutions with BSL-3 containment frequently do not follow the advice of the NIH Office on Biotechnology Activities:

Table 4. Content of the Minutes – (Non)Adoption of NIH Advice

Question	Result:		
Does the IBC review both biohazard research and rDNA, as preferred by NIH?	60% Yes	33% review rDNA only	7% provided insufficient information
Do the minutes routinely identify organisms (pathogens), as instructed by NIH?	27% Yes	73% No	-
Do they routinely describe the host/vector systems used, as instructed by NIH?	12% Yes	88% No	-

ACCIDENTS AND OTHER INCIDENTS PROMPTED BY EXPANSION OF BIOLOGICAL WEAPONS AGENT RESEARCH UNDER THE BUSH ADMINISTRATION

Accidents and other safety and security problems have resulted from expansion of research involving biological weapons agents. These include laboratory-acquired infections with biological weapons agents, unauthorized persons handling biological weapons agents, failure to account for stocks of biological weapons agents, and other problems.

It should be initially noted that the public's right to know about lab accidents is largely ignored, and information on them is very difficult to acquire. The Centers for Disease Control refuses all FOIA requests for such information (see "Inadequate Transparency") and the NIH Office of Biotechnology Activities has not produced its data (see "Failure of NIH Oversight"), although there is good reason to question its reliability, if NIH data exists (see "Failure of Institutional Biosafety Committees"). In general, it is only possible for the public to acquire information about laboratory mishaps in the limited number of cases where labs are a) subject to open records rules sufficiently powerful to enable access to accident documentation, and b) have policies to record incidents. There is mounting evidence that, at many facilities, there have been *de facto* policies not to record accidents, including accidents with biological weapons agents (see "Emerging Questions about Laboratory Safety and Security Programs").

Texas A&M University (TAMU) is a Department of Homeland Security National Center of Excellence in study of biological weapons agents, and is the lead institution in the DHS National Center for Foreign Animal and Zoonotic Disease Defense. Through the Texas Public

Information Act, and significant pressure on TAMU officials, it was established that in 2006 and 2007 the University committed numerous violations of the Bioterrorism Act of 2002 (implemented by the Select Agent Rule). The most serious of these included an unreported lab-acquired infection with *Brucella sp.* and multiple unreported exposures to Q fever (*Coxiella burnetti*). CDC investigations prompted by Sunshine Project news releases documented additional serious violations that include more unreported lab exposures and irregularities in accounting for biological weapons agents and, importantly, that TAMU repeatedly permitted access to and handling of biological weapons agents by persons lacking federal permission to do so. In fact, the brucellosis victim was one such person.

In addition to the incidents at Texas A&M, analysis of biosafety committee minutes show other accidents involving select agents and/or BSL-3 labs:

- At the University of Wisconsin at Madison in 2005 and 2006, researchers handled genetic copies of the entire Ebola virus (called "full length cDNAs") at BSL-3, despite the fact that the NIH Guidelines require handling at BSL-4 because the genetic constructs had not been rendered irreversibly incapable of producing live virus. The University of Wisconsin at Madison Institutional Biosafety Committee reviewed and approved this research despite federal Guidelines to the contrary. The problem was not detected by NIH. In fact, NIH funded the research.

- There is evidence that a situation similar to Wisconsin's exists or existed at Tulane University in New Orleans, Louisiana, which also does not have appropriate labs for such research. Tulane officials refused a half dozen requests to clarify the research, again with Ebola cDNAs as well as constructs for Lassa fever virus, another BSL-4 hemorrhagic fever agent;

- At the University of Texas at Austin in April 2006, human error and equipment (centrifuge) malfunction combined in an incident in a BSL-3 lab handling potentially very dangerous genetically-engineered crosses between H5N1 "bird flu" and typical (H3N2) human influenza. The researcher was placed on drugs, the lab shut down and decontaminated. The University did not report the incident to the federal government and has since produced conflicting accounts of what exactly happened;

- In mid-2003, a University of New Mexico (UNM) researcher was jabbed with an anthrax-laden needle. The following year, another UNM researcher experienced a needle stick with an unidentified (redacted) pathogenic agent that had been genetically engineered;

- At the Medical University of Ohio, in late 2004 a researcher was infected with Valley Fever (*Coccidioides immitis*), a BSL-3 biological weapons agent. The following summer (2005), a serious lab accident occurred that resulted in exposure of one or more workers to an aerosol of the same agent;

- In mid-2005, a lab worker at the University of Chicago punctured his or her skin with an infected instrument bearing a BSL-3 biological weapons agent. It was likely a needle contaminated with either anthrax or plague bacteria;

- In October and November of 2005, the University of California at Berkeley received dozens of samples of what it thought was a relatively harmless organism. In fact, the samples contained Rocky Mountain Spotted Fever bacteria, classified as a BSL-3 bioweapons agent because of its potential for transmission by aerosol. As a result, the samples were handled without adequate safety precautions until the mistake was discovered. Unlike nearby Oakland Children's Hospital, which previously experienced a widely reported anthrax bacteria mixup, UC Berkeley never told the community;

In addition to lab-acquired infections and exposures, other types of dangerous problems have occurred, such as unauthorized research, equipment malfunction, and disregard for safety protocols:

- In February 2005 at the University of Iowa, researchers performed genetic engineering experiments with tularemia bacteria without permission. They included mixing genes from tularemia species and introducing antibiotic resistance;

- In September 2004 at the University of Illinois at Chicago, lab workers at a BSL-3 facility propped open doors of the lab and its anteroom, a major violation of safety procedures. An alarm that should have sounded did not;

- In March 2005 at the University of North Carolina at Chapel Hill, lab workers were exposed to tuberculosis when the BSL-3 lab's exhaust fan failed. Due to deficiencies in the lab, a blower continued to operate, pushing disease-laden air out of a safety cabinet and into the room. An alarm, which would have warned of the problem, had been turned off. The lab had been inspected and approved by the US Army one month earlier;

- In December 2005 at the Albert Einstein College of Medicine at Yeshiva University in New York City, three lab workers were exposed (seroconverted) to the tuberculosis bacterium following experiments in a BSL-3 lab. The experiments involved a Madison Aerosol Chamber, the same device used in the February 2006 experiments that resulted in the Texas A&M brucella case;

- In mid-2004, a steam valve from the biological waste treatment tanks failed at Building 41A on the NIH Campus in Bethesda, Maryland. The building houses BSL-3 and BSL-4 labs. Major damage was caused, and the building was closed for repairs;

- In April 2007, a centrifuge problem exposed several lab workers at the University of Texas Health Science Center in Houston to anthrax;

- Also in April 2007, three lab workers entered a laboratory studying tularemia at the University of Texas at San Antonio to repair faulty air filters. The workers did not wear respiratory protection and handled the filter equipment without gloves.

It is very important to note that these and other examples of lab accidents are drawn from biosafety committee meeting minutes of institutions that actually record such incidents in records that are (at least nominally) available to the public. Often, this is not the case, such as that of

Texas A&M, which only released accident information under extreme pressure. Thus, the sample of institutions named above is (mostly) skewed toward those that have been more open about their accidents than others.

FAILURE OF VOLUNTARY COMPLIANCE UNDER NIH GUIDELINES: GAPS IN OVERSIGHT OF GOVERNMENT AND CORPORATE LABS

There are major gaps in the oversight system for government and corporate labs. Generally, Institutional Biosafety Committees (IBCs) are only required at institutions currently receiving NIH funding for rDNA research, meaning that the vast majority of the private sector is left out. In addition, although some federal agencies mandate IBCs at their own labs or research they fund, these regulations and rules are not enforced.

Sunshine Project requests for IBC minutes and Freedom of Information Act requests to NIH have recently revealed the extremely low level of voluntary compliance by private industry. This is the case with both smaller biotechnology concerns and large pharmaceutical and biomedical companies.

Only 5 of the top 20 independent (as of 2004) biotechnology companies have IBCs registered with NIH, and of those 5, only two disclose their biosafety minutes to the public as required by the NIH Guidelines. Both of these companies are based in Cambridge, Massachusetts, where compliance with the NIH Guidelines is required by local ordinance, further suggesting that voluntary mechanisms are insufficient to bring about compliance:

Table 5: IBC Compliance Record of Leading US Biotechnology Companies

Top 20 US Biotech Companies ('04)	2004 Revenue (US$ millions)*	Employees*	Does company have an NIH-registered IBC? **	Actually complies? (i.e. has responded to requests under the NIH Guidelines)***
Amgen	10550	14,400	NO	no****
Genentech	4621	7,646	YES	NO
Biogen IDEC	2212	4,266	NO	no
Genzyme	2201	7,000	YES	YES
Chiron*****	1723	5,400	YES	NO
Gilead Biosciences	1325	1,654	NO	no
MedImmune******	1141	1,823	NO	no
Cephalon	1015	2,173	NO	no
Millennium Pharma	448	1,477	YES	YES
Genencor	470	1,271	YES	NO
ImClone Systems	389	866	NO	no
Celgene	378	766	NO	no
MGI Pharma	196	282	NO	no
Nabi Biopharma	180	727	NO	no
Regeneron Pharma	174	730	NO	no

Enzon Pharma	170	n/a	NO	no
Ligand Pharma	169	359	NO	no
Acambis (US/UK)	157	270	NO	no
InterMune	151	326	NO	no
Vertex	103	736	NO	no
Overall Findings		Only 16% (8,500 out of 52,000+) of biotech employees work at a compliant company	Only 25% (5/20) of top biotech companies have registered IBCs.	In reality, only 2 (of 5) companies with NIH-registered IBCs actually comply, for an overall compliance rate of 10%

*Source: Wikipedia/MedAdNews.
** Source: List of NIH Registered IBCs provided by NIH (FOIA Case 32063, reply of 27 February 2006).
*** Source: Replies to survey letters sent by the Sunshine Project in 2006.
**** In order to be compliant, a committee must be registered.
***** Recently acquired by Novartis.
****** Recently acquired by AstraZeneca

Voluntary compliance by large enterprises is no better. Companies including Merck, Bristol-Myers Squibb, DuPont, Pfizer, BASF, Schering-Plough, and Roche (at all but one site) all at one time had registered IBCs; but no longer participate in the federal oversight system.

Although Institutional Biosafety Committees are supposed to be the local bulwark against misapplication of biological research, voluntary compliance of the private sector with the NIH Guidelines is virtually nonexistent.

There are also local oversight problems at government labs. The Department of Homeland Security's Plum Island Animal Disease Center in New York replied to requests for its IBC meeting records in both 2004 and 2006 by stating that it had no records to provide. Two other agencies require compliance with the NIH Guidelines: USDA by regulation, and DOE by rule.[5]

The existence of the DOE rule does not mean that its facilities actually follow it and, in fact, some labs don't. Until the Sunshine Project drew attention to the issue, neither Argonne National Laboratory near Chicago, home of a NIAID-funded Regional Biocontainment Laboratory nor Pacific Northwest National Laboratory (Richland, WA), had registered IBCs. The National Renewable Energy Laboratory (NREL, located in Golden, CO) has an NIH-registered IBC. But in response to a request for its minutes, NREL stated that the NIH Guidelines "*are not applicable to NREL*". Operated by Battelle Memorial Institute and Midwest Research Institute, the federal lab asserted that it "*voluntarily follows the Guidelines as an industry best-practice*",[6] yet it did not follow the provision requiring release of committee minutes.

Lawrence Livermore National Laboratory in Livermore, CA recently delayed nearly 17 months before replying to a request for its IBC minutes, and then provided heavily and inconsistently redacted material that suggests significant problems handling biological weapons agents and with its laboratory equipment. The redactions are so heavy, however, that a more specific description of the problems cannot be discerned.

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[5] USDA's regulation is 7 CFR 3015.205(b)3, applying to USDA-sponsored research. DOE Rule N 450.7, applying to DOE labs.

[6] Letter from NREL to the Sunshine Project, 19 February 2004.

As of early 2004, Idaho National Laboratory's IBC had only met once in its history (in 2002), when it discussed what an IBC is and did not review research. The lab did not honor 2006 requests for its minutes, despite NIH Guidelines and FOIA requirements to do so.

The US Department of Agriculture has several labs with IBCs registered with NIH, as required by USDA regulation. All of these sites have been asked for their records twice by the Sunshine Project. Only one of them (Beltsville Agricultural Research Center), produced IBC meeting minutes in response to these requests.

USDA also makes biodefense grants; but does not enforce its own biosafety regulations in doing so. Formerly, all recipients of USDA biotechnology research grants were required to sign and submit a Research Assurance Statement certifying that they would comply with the NIH Guidelines and, thus, form and operate a local IBC to review research.

In February 2001, however, USDA's Agricultural Research Service (ARS) stopped asking grantees to make this certification. The Sunshine Project filed a FOIA request for ARS' policy memoranda related to this decision. Under FOIA, ARS replied that it has no responsive records. While other USDA grantmaking agencies continue to use a research assurance statement, in reply to a FOIA request, USDA estimated that it has statements certifying compliance on file for only 50% of relevant grants.

FAILURE OF BIOSAFETY VOLUNTARY COMPLIANCE: FAILURE OF INSTITUTIONAL BIOSAFETY COMMITTEES

In addition to the oversight gaps among private sector and government labs, there is widespread failure by institutions with registered IBCs to actually operate committees that meet and attend to their duties. The Sunshine Project has been publicly documenting these failures since 2003,[7] shortly after the NRC's Fink Committee published its report *Biotechnology Research in an Age of Terrorism*, which recommended that IBCs form the front line for the safety and security of research with biological weapons agents.

The Sunshine Project's report *Mandate for Failure: The State of Institutional Biosafety Committees in an Age of Biological Weapons Research* (2004) and a 2006 survey (in press) document serious transparency failures among IBCs, but equally alarming, we have consistently found IBCs that do not meet and do not review research. Some examples include:

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[7] See: *Mandate for Failure: The State of Institutional Biosafety Committees in an Age of Biological Weapons Research* (2004), URL: http://www.sunshine-project.org/biodefense/ibcreport.html and the *Biosafety Bites* series of short reports (2004-2007), URL: http://www.sunshine-project.org/ibc/bb2006.html

- The IBC of the University of Georgia is responsible for reviewing research at the USDA Southeast Poultry Research Laboratory (SEPRL) in Athens, GA. SEPRL is where the first experiments to bring back to life the major genes of 1918 influenza occurred. In 2003, the Sunshine Project asked the University for the minutes of its IBC review of these experiments. It transpired that no minutes existed because no IBC review was performed of the research, which involved creation of an extraordinarily dangerous and novel influenza strains. In fact, the University of Georgia does not appear to have ever held an IBC meeting until 23 March 2006, a few days after the Sunshine Project again asked for its minutes. The meeting was organizational, with members introducing themselves to one another and discussing what an IBC's responsibilities are.

- The Rockefeller University in New York City is a major biomedical research institute. Asked for minutes of its IBC in 2004, the University refused to provide any records yet peremptorily demanded that the Sunshine Project state that it has "*fully complied*" with the request for minutes. Eventually, Rockefeller was forced to reveal that its IBC had met once in 2003, to review a single project (and nothing else). The most recent meeting before that was in 1998. In 2006, Rockefeller refused to reply to renewed requests for its IBC minutes.

- Battelle Memorial Institute, headquartered in Columbus, Ohio, is a gigantic science contractor with an emphasis on defense research, including classified programs. Battelle is overwhelmingly funded by the US government, which provides it with US $1.3 billion per year in grants, plus hundreds of millions in payments for services. For a period covering four and a half years, from January 2000 through mid-2004, Battelle could not produce a single page of minutes of IBC meetings. In the same time period, Battelle only once reported to the NIH Office of Biotechnology Activities. The late 2001 report was made shortly after the *New York Times* ran a story saying that Battelle would be the site of a project to genetically engineer a vaccine-resistant strain of anthrax. Battelle has "registered" and "deregistered" its IBC with NIH as a matter of convenience. Since 2004, Battelle has produced minutes indicating that its IBC has met six times, however, its discussions have primarily concerned organizational matters. It has reviewed a handful of protocols, the substance of which it refuses to make public.

- The Southwest Foundation for Biomedical Research (SFBR) in San Antonio, Texas, operates the county's only private BSL-4 laboratory and it refuses to produce documentation of its IBC actually reviewing projects. In 2004, the Sunshine Project requested minutes of all SFBR IBC meetings since the end of 1999. In July 2004, SFBR replied with what it says is the entirety of its IBC minutes, which consisted of a short list of project titles that fit on a single page of paper. SFBR could not name any date on which its IBC had met. The entirety of its correspondence with the NIH Office of Biotechnology Activities (OBA) in this 4 1/2 year period was one letter consisting of two sentences (and no substance). In 2006, SFBR replied to another request for its IBC records with another page of paper, containing the titles of four projects and the names of eight persons on its IBC. This allegedly reflected all IBC activity from 8 July 2004 through 13 April 2006. As with its 2004 reply, there is no significant reflection of any actual IBC meeting(s), protocol review, laboratory safety review, discussion of safety incidents and response, consideration of dual-use aspects of research, or any other biosafety business.

- Asked for its IBC minutes in 2004, Emory University in Atlanta, Georgia could not produce minutes reflecting committee review of a single research project. Despite its huge research portfolio, at none of its meetings from 2001 to 2004 did the Emory IBC review biosafety of any project. Instead, Emory's IBC hears general presentations from staff about biological, chemical, and radiological safety. The minutes of Emory's meetings indicate that, after hearing the presentations, members of the IBC have only rarely had any questions or comments to make.

• Utah State University states that its IBC approved at least 48 research protocols before the committee was ever organized. Utah State could not produce any minutes of meetings of its IBC, except those of an emergency meeting - its first ever - called after the Sunshine Project requested its IBC minutes. At its first meeting, Utah State's IBC leaders provided the committee members with a list of the projects that the committee had approved over the previous six and half years - before it actually existed. Utah State University has a virology institute that actively advertises its large collection of biological weapons agents and its knowledge of how to manipulate them.

• The Venter Institute, formerly known as The Institute for Genomic Research in Rockville, MD, has historically not had a functional IBC to review its research. (This is discussed in more detail in "Failure of NIH Oversight".). Despite that fact, a Venter-led consortium studying synthetic biology risks recently suggested that IBCs could take the lead in review of synthetic biology experiments.

• Mt. Sinai Medical Center in New York City vehemently resisted requests for its IBC minutes, publicly declaring that they were available only on a "*need to know basis*". After a long correspondence, Mt. Sinai eventually revealed that it had no IBC meeting minutes because its biosafety committee did not meet;

• A rare private company with a registered IBC, since 2002, AlphaVax (Research Triangle Park, NC) has received approximately $42 million in NIH research grants. As of late 2006, however, AlphaVax's (IBC) hadn't met for almost three and a half years. AlphaVax conceded that its IBC had not held a meeting since May 2003; but the company maintains records that state otherwise. AlphaVax sends out safety documents by e-mail to IBC members and then writes a memo to the file that grants blanket IBC approval for such research. For example, on 12 July 2006, over three years after its last IBC meeting, AlphaVax recorded the following in a memo: "*On July 12th 2006, the AlphaVax Institutional Biosafety Committee met and reviewed your amendment to the recombinant DNA registration document entitled 'Registration Document for Recombinant DNA Studies' ... You may proceed with this work immediately.*" No meeting took place. Other such memos were written in 2003 and 2004 for which no IBC meeting took place.

• In response to a 2004 request for its IBC minutes, North Carolina State University could only produce an e-mail from the outgoing committee chair, a junior faculty member moving to a position elsewhere, stating that he (and not the committee) had reviewed and approved all research protocols for the preceding year and that nothing had required the committee's attention. In 2006, it produced a jumbled set of documents indicating an attempt to organize a functional IBC, but not the records of an effective committee.

• In 2004, the Sunshine Project repeatedly asked the Pennsylvania State University Medical Center in Hershey for its IBC minutes, citing the NIH Guidelines as usual. After a third request, the Director of the Office of Research Affairs replied with a letter asking what NIH Guidelines we were talking about.

- The University of South Carolina can only produce evidence of its IBC having met twice in its history. The first meeting was on 7 July 2004, when the committee discussed the Sunshine Project's three requests for its minutes (the University had yet to reply). The meeting was not prompted by NIH OBA or by other biosafety business, rather, it came about as a result of a public inquiry. Asked for it minutes again in 2006, it produced a single sheet of paper. At this one additional meeting, held in September 2005, the IBC was still discussing the Sunshine Project's request for its minutes made more than a year previously. It was also resolving problems with its membership. Its minutes reflect no serious biosafety business. The President of the University of South Carolina sits on the National Science Advisory Board on Biosecurity (NSABB).

- In 2004, the University of Hawaii produced a few half pages of IBC minutes not reflecting protocol review and suggesting that the committee viewed its main function as being that of assisting a private company with field trials of genetically engineered crops (a task beyond the federal mandate of IBCs). In 2006, Hawaii produced minutes that list protocols by number, indicating that they have been approved, but providing none of their content or any indication of active committee discussion and consideration of the projects.

- The University of Texas Southwestern Medical Center in Dallas places substantive information about IBC review of projects, if any such information exists, in annexes to minutes of its IBC meetings, which typically simply indicate that meeting occurred and who attended. Whether the committee actually discharges its responsibilities is impossible to determine. Other institutions, such as Princeton University, Indiana University, and the University of Delaware, among others, take similar approaches of blacking out their minutes or not recording the substance of meetings to begin with. It cannot be said with certainly if these are efforts to prevent disclosure or to conceal ineffective committees.

These are only some of the IBCs that do not meet and/or do not fulfill their mandate to supervise research. While a relatively small number of committees do regularly meet and review research, many do not. NIH seldom, if ever, detects IBCs that fail to exercise their responsibilities. The only regular reporting requirement to NIH under the NIH Guidelines is for IBCs to provide a roster of members and their résumés. No other records, such as minutes, research proposals and protocols, documentation of reviews, protocol renewals and amendments, etc. are routinely submitted to or reviewed by NIH, giving NIH no vantage point at all from which to assess the effectiveness of committees. In any event, NIH has shown little curiosity about the truth.

FAILURE OF BIOSAFETY VOLUNTARY COMPLIANCE: FAILURE OF NIH OVERSIGHT

The NIH Office of Biotechnology Activities (NIH OBA) is in charge of the IBC system of local committees that are now supposed to also oversee dual use research. Since 2003, the Sunshine Project has lodged approximately 150 written complaints with NIH OBA for noncompliance by IBCs. In addition, NIH OBA has been copied on hundreds of letters and e-mails between the Sunshine Project and IBCs across the US that do not have committee meetings, that refuse to produce minutes, that refuse to clarify apparent problems (such as no evidence of review of research, noncompliant committee membership, etc), and other problems. The Sunshine Project has also filed approximately 16 Freedom of Information Act requests with OBA for a variety of records, including accidents reports by IBCs, correspondence with IBCs, and other records.

On balance, these complaints do not appear to have improved the functioning of the system and, although IBCs that do not execute their responsibilities have been repeatedly brought to the attention of NIH OBA, it has not significantly improved the overall functioning and reliability of the system. FOIA requests indicate one reason why: NIH OBA, which has no regulatory authority, often has no significant contact, for years on end, with committees that it is said to oversee, with the exception of "annual reports" from IBCs that merely consist of a cover letter attached to résumés of committee members. The annual reports do not provide documentation of the committee actually meeting and exercising its responsibilities. In some cases, even these *pro forma* reports are not filed. Despite that fact, such nonreporting IBCs have remained on the NIH roster of active committees for years.

In some cases where the Sunshine Project has filed complaints, NIH has opened "investigations" that have had little to no effect on the IBC's compliance. In others, institutions have removed their committees from the NIH roster rather than respond to the concerns raised by the complaint. For example:

Until July 2004, the Venter Institute (formerly known as the Institute for Genomic Research, or TIGR) had held only two IBC meetings in it history, despite its 400 research employees who typically have about 150 active projects, including work sequencing biological weapons agents. One of the IBC meetings didn't assess biosafety, it was dedicated to discussing the format of the committee's paperwork. In July 2004, the Sunshine Project lodged a complaint with NIH OBA because an IBC that is not meeting and not reviewing projects is obviously not exercising its responsibilities.

FOIA requests later revealed that about three months after the complaint, on 25 October 2004, NIH OBA began to act. In sent a letter to the Venter IBC Chair, NIH OBA asked Venter Institute (then TIGR) a number of questions. Most important among them was if its IBC was reviewing and overseeing research.

On 13 December 2004, Venter Institute replied. It stated that the Institute "*received its first NIH funded project involving recombinant DNA in early 1996,*" meaning that the IBC should have been overseeing research for nine years at that point. But the Institute admitted, "*During its first years, the TIGR IBC did not formally meet*".(7) In other words, the committee did not function, not bothering to even meet once until 2002.

Then came the following: "*we have identified nine [9] projects that were not properly registered or reviewed by the TIGR IBC*". This was an admission that the IBC was failing to identify and review research. In addition, the Institute stated that there were 116 more genetic engineering projects active in its labs that, it claimed, did not require IBC oversight. Venter Institute said that it was gathering information about the unreviewed projects and would have the IBC review them *ex post facto* in January 2005.

The minutes of the January 2005 Venter IBC meeting, a meeting that likely would never have been held absent the Sunshine Project's complaint, reveal that the unreviewed projects included work on biological weapons agents. The projects included work with the entire genome of strains of plague (*Yersinia pestis*), as well as glanders (*Burkholderia mallei*), melioidosis (*Burkholderia pseudomallei*), and valley fever (*Coccidioides immitis*) bacteria. In addition, there were two NIH-funded biodefense "pathogen genomics" projects for which the minutes do not reveal what the specific pathogens are in use.

Seven Venter Institute investigators were responsible for the (at least) five projects involving both recombinant DNA and biological weapons agents that were not reviewed by the IBC. These include senior investigators in the Venter pathogen, parasite, and microbial genomics groups.

NIH OBA was thus presented with an alarming situation that demanded a response. A major recipient of NIH recombinant DNA and biodefense funding had failed to maintain an Institutional Biosafety Committee that functioned and did not properly identify, review, or oversee research. While none of the projects that Venter Institute admitted to have failed to properly oversee involved large quantities of pathogens, the simple fact of the matter was that Venter's noncompliance was obviously systemic, penetrating to the leadership of the organization and ongoing for many years. In addition, it should have been apparent to NIH OBA that the government would not have detected the problems, because Venter (like other IBCs) had no effective reporting requirements.

The penalty for violating the NIH Guidelines can be loss of NIH research funding. Instead, an OBA staff member called Venter to confirm that the IBC performed the after-the-fact review of the nine offending projects. There is no evidence from the correspondence between OBA and Venter that OBA made any effort to independently verify Venter's claims about the 116 other projects, nor to identify and assess other past projects funded by NIH, other government agencies, or otherwise that were not properly overseen.

On 13 May 2005, NIH OBA sent Venter Institute a letter thanking it for providing "*its helpful response and attention to compliance*" and declared that Venter's reply "*satisfactorily addresses the issues*". Case closed. In June 2005, NIH OBA then announced the appointment of one of Venter's scientists responsible for the noncompliant research to the National Science Advisory Board on Biosecurity (NSABB). Thus, NIH OBA did not merely shrink away from sanctioning Venter for noncompliance, it actually rewarded the Institute with an important policy advisory position.

In reality, nothing actually changed at the Venter Institute after NIH's "investigation." In 2005 and 2006, Venter continued to receive NIH funding, projects led by some of the same principal investigators whose previous projects were not overseen by an IBC. Other federal agencies also continued their funding

In July 2006, Venter responded to another Sunshine Project request for its minutes. Although NIH OBA says it requires IBCs to meet at least once a year, the Venter IBC had no meeting minutes subsequent to the January 2005 that was only held because it was forced to as a result of the Sunshine Project's complaint.

In a similar situation involving the Salk Institute, the Sunshine Project lodged a complaint against Salk's inactive IBC on 1 September 2004. Two years later, NIH OBA resisted a FOIA request for the investigation file; but a request for committee minutes to Salk revealed that as of 13 September 2006 the Institute still had not conducted a review of its research portfolio to determine how many projects it was failing to oversee.

In November 2006, the Sunshine Project lodged complaints against 40 private sector IBCs that refused to honor requests for minutes of their committees. The results to date are:

Table 5: Result of November 2006 Complaints to NIH Concerning Private Sector IBCs

Outcome	**Number (n=40)**
1. Company provided (at least some) IBC minutes.	20% (8)
2. Company "deregistered" or "deactivated" the IBC from NIH registry and did not provide minutes.	42.5% (17)
3. Company said it did not receive two or more requests sent to the IBC address provided by NIH.	12.5% (5)
4. Company stated research was suspended.	2.5% (1)
5. No reply to date (1 Sep 2007) from NIH OBA	22.5% (9)

NIH OBA lacks regulatory power and we cannot identify any case in which it has suspended funding to an institution for IBC violations. In addition, NIH OBA does not collect any significant reports from the IBCs it is supposed to oversee. It is thus toothless and frequently uninformed, and as a result, its inquiries usually do not appear to be considered to be of importance by institutions that receive them.

PROBLEMS WITH CDC OVERSIGHT OF BIOSECURITY: INADEQUATE INSPECTION PROCEDURES

It is apparent that CDC inspections have not identified significant problems at laboratories handling biological weapons agents. This is clearest at Texas A&M University, where the Texas Public Information Act has caused release of a large amount of documentation from TAMU's biosafety and biosecurity program and CDC's inspections. CDC's cause inspections of Texas A&M in April and July of this year revealed numerous problems that existed but were not detected during CDC's previous routine inspections.

Routine CDC inspection did not detect the fact that TAMU had permitted unauthorized persons to handle biological weapons agents, even though the incident in which an unauthorized researcher contracted brucellosis occurred before CDC's 2006 inspection at TAMU. Other problems CDC inspectors failed to discover include a researcher who stuck him or herself with a *Brucella*-laden needle in 2004, multiple exposures to Q fever in 2006, and inadequate ventilation of major piece of lab equipment (an aerosol chamber) used with biological weapons agents. A number of additional missed violations are documented in the reports of the CDC cause inspections following the Cease and Desist Orders issued to TAMU.

Texas A&M's obvious lack of candor with CDC's inspectors certainly appears to have been a contributing factor, however, the Select Agent program should have detected many of these problems.

One factor that may be relevant is CDC's use of contractors such as SRA International's subsidiary the Constella Group. Contractors perform inspections (under CDC direction, the agency states), and handle some Select Agent Program functions at CDC offices. In addition, private contractors from Constella appear to play a major role in accident reporting. In April 2007, when the University of Texas at San Antonio made a mandatory (Form 3) report of lab workers being exposed to tularemia, they submitted it to a Constella Group contractor, and not a federal official.

Another serious issue concerning CDC inspections is that it is apparent that there are many, perhaps very many, biological weapons agent facilities that do not have NIH-registered Institutional Biosafety Committees (IBCs). For example, the Midwest Research Institute in Kansas and Florida. This is a problem because it is the NIH Guidelines, and not the Select Agent Rule, that describe IBCs and establish the ground rules under which the committees operate. As IBCs are the local committees that should oversee dual use research, the basis on which CDC can conclude that oversight is adequate at a facility whose safety committee does not participate in the federal IBC system is very unclear, particularly in view of the fact that NIH itself does not enforce IBC rules.

In addition to a number of the problems at Texas A&M, the Sunshine Project and news media have uncovered other laboratory accidents reportable to the CDC under the Select Agent Rule (see *Accidents and Other Incidents Prompted by Expansion of Biological Weapons Agent Research*). It is impossible to determine if these incidents were reported to and/or detected by CDC inspections because CDC refuses FOIA requests concerning the Select Agent Program (see *Inadequate Transparency*).

PROBLEMS WITH CDC OVERSIGHT OF BIOSECURITY:
INADEQUATE COVERAGE OF NUCLEIC ACIDS

A major flaw in the existing Select Agent Rule is that, as interpreted by the CDC, it fails to adequately cover nucleic acids (DNA, RNA) that can be use to produce select agents.

For many viruses, including several select agent viruses such as 1918 influenza, H5N1 avian influenza, and Ebola viruses, it is possible to produce fully infectious virus from nucleic acids comprising the virus genome. This can be accomplished in short periods of time, in some cases in less than two days and without any specialized equipment that would not be typically present in a university or private sector virology lab.

The Select Agent Rule contains language covering nucleic acids that can produce select agents (*"Nucleic acids that can produce infectious forms of any of the select agent viruses..."* are classified as select agents). But contrary to the language of the Rule, CDC has interpreted it to cover only those nucleic acids that are, in effect, full-fledged disease agents and which can cause infection through injection, inhalation, or exposure without any further manipulation.

These flaws effectively enable unregulated possession of several select agent viruses. The threat posed by this flaw is increasing in direct proportion to the rapid development of DNA synthesis technology and the DNA synthesis industry as well as the related field of synthetic biology, which is dramatically decreasing the cost, time, and difficulty of producing a nucleic acid that can be used to produce a select agent.

This is not a theoretical concern. It is currently happening in US labs.

Advances in DNA sequencing technology and in the related field of synthetic biology, where scientists construct living systems from nucleic acid building blocks, are heightening the chances that these kinds of biotechnology could be used for biological weapons purposes. While members of the DNA synthesis industry and some synthetic biologists have indicated their concern and even openness to discuss regulation, for instance through a "Select DNA (RNA) Rule", there does not appear to have been any practical movement forward by CDC on this issue, and full length nucleic acids, as well as those encoding major portions of select agents, remain outside the Select Agent Rule as interpreted by the CDC.

PROBLEMS WITH CDC OVERSIGHT OF BIOSECURITY

INADEQUATE TRANSPARENCY

In the experience of the Sunshine Project, CDC simply denies, usually immediately, all FOIA requests for records related to the Select Agent Program. The agency does not even typically search for responsive records and attempt to identify applicable exemptions, rather, it simply denies requests on the basis that they have some bearing on CDC oversight of research involving biological weapons agents. Numerous journalists and several other nongovernmental organizations have told the Sunshine Project that they have had the same experience.

CDC's wall of denial of information about select agent research and oversight plainly exceeds what it is authorized to withhold under law. Recently, it has begun to issue so-called "Glomar responses" to FOIA requests for information about accident investigations. Preposterously, last week the Sunshine Project received a letter from CDC refusing to confirm or deny the existence of the report of its investigation of Texas A&M, when the CDC site visits to College Station and the content of the report was front page news. Even the report itself was on the *Dallas Morning News* website, among others. None of its information created any security threat at Texas A&M.

The Sunshine Project has appealed CDC FOIA denials to no avail. We do not have the resources to conduct federal litigation, the only other option left to us. While some records, and parts of other records may be legitimately withheld, these are mainly items that identify the precise location or would divulge specific physical security measures to protect select agents.

The Sunshine Project is experienced handling open records requests with hundreds of US labs that possess biological weapons agents. Our experience is that while security concerns are frequently raised in relation to open records requests, if the agency (or lab) is informed about select agent issues and is willing to listen, the concerns are quickly resolved. The Sunshine Project certainly has not, and we unaware of any other requester, ever insisting upon release of physical security information that would facilitate theft or diversion of a select agent. In any event, such information is amply protected from disclosure.

EMERGING QUESTIONS ABOUT LABORATORY SAFETY AND SECURITY PROGRAMS AND POSITIVE CORRELATION BETWEEN TRANSPARENCY AND INCIDENT REPORTING

It is both encouraging and worrisome to note that there has been an uptick in reports of accidents with biological weapons agents to CDC in 2007, according to a recent report by the Associated Press. Our research suggests the AP report is correct. The Sunshine Project has found evidence of at least seven reports to CDC in 2007 of biological weapons agent incidents in Texas alone, and our research is expanding to other states.

Since the Texas A&M story became public, we have asked a number of institutions for all biosafety records of possible or actual exposures to significantly pathogenic agents (risk group 2 or higher) since 2000. Texas A&M itself has led the way, and now reports its accidents to CDC and releases documentation to the public without squabble. Texas A&M alone has filed several of the required Forms 3s.

More ambiguous is the reply of two Texas institutions with long-standing biological weapons agent programs, the University of Texas at San Antonio (tularemia) and the University of Texas Health Science Center at Houston (anthrax). Both universities produced reports to CDC of logical weapons agent accidents in response to our request, however both reports post-dated the Texas A&M story. The positive interpretation is that these institutions are reporting accidents. But both institutions also denied having any records of any incidents with biological weapons agents, even small ones or false alarms, prior to April 2007. This suggests that there may be unreleased records being kept secret, or that the may have had *de facto* policies of not recording accidents prior to spring 2007.

On one hand, it is encouraging to see evidence of a positive correlation between transparency (at Texas A&M) and reporting by other institutions – in Texas and, as the AP report may indicate, elsewhere.

On the other hand, two other Texas institutions with BSL-3 labs, the University of Texas at El Paso and the University of Texas Health Center at Tyler, both denied having any records whatsoever on any possible or actual exposures to risk group 2 or higher agents for a period of seven years. Risk group 2 includes many organisms that are far less dangerous that most biological weapons agents. Texas Tech University and its Health Science Center have also replied that they have no incident records whatsoever. Similarly, the University of Georgia (one of the few replies outside Texas received so far) denies having any records of any even minor lab incidents since 2000, with the exception of two lab exposures to a non-biological weapons agent, about which the school refuses to release information.

The credibility of such responses is not high. A possible explanation for the professed lack of relatively routine lab safety records is that these institutions have dysfunctional laboratory safety programs that do not detect, investigate, or record lab incidents. Alternatively, they may not be producing responsive records in the same manner that Texas A&M initially treated the Sunshine Project. The initial reply by Texas A&M to a nearly identical request for its accident records produced a single page of paper. After several months of correspondence, including involvement of the Brazos County, Texas District Attorney, who is charged with enforcing the Texas Public Information Act, Texas A&M's reply has now grown to approximately 3,000 responsive pages whose existence it initially denied.

Detection, investigation, and reporting of lab incidents involving biological weapons agents merits increased attention. What can be said now is that there has been a positive correlation between the transparency that has been brought about at Texas A&M and incident reporting by other Texas institutions that handle biological weapons agents. Serious problems remain, however, evidenced by the reluctance of institutions to make their incidents public and the dubious denials of other institutions of having records of biological accidents all.

RECOMMENDATIONS

1. Neither the United States nor any other country presently needs 400 labs or 15,000 people conducting biological weapons agent research. Our country would be safer and more secure with a smaller, more transparent, and more rationally organized program. *Therefore my first and most important recommendation is that Congress reduce the number of US labs and people handling biological weapons agents*.

2. The proliferation of BSL-3 and BSL-4 laboratories across the United States since 2002 is greater than what our country needs and what its safety and security net can absorb. One-off NEPA processes are not sufficient or appropriate for this national-scale problem. *Congress should impose a moratorium on federal funding for construction and commissioning of new biodefense labs. No new construction contracts should be issued, and no new labs should open until a comprehensive needs assessment is performed by the Government Accountability Office*.

3. *Congress should suspend or completely terminate some new laboratory projects currently underway.* Prime candidates include but are not limited to the oversized and overblown National Bio and Agro-Defense Facility (in site selection), the unpopular and divisive Boston University National Biocontainment Laboratory (under construction), and the University of Hawaii Regional Biocontainment Lab (in design), which is years late and 50% over budget before groundbreaking.

4. Voluntary compliance with proper laboratory practices for biodefense labs is unwise and does not work. *Congress should make compliance with the BMBL (CDC lab safety manual) and federal rDNA Guidelines truly mandatory, by making it a matter of law.*

5. Research review at the local level is currently very uneven, sometimes does not take place at all, and the system involves related, fragmentary charges operating under a

divided federal oversight system. *Congress should require that all institutions operating BSL-3 or higher labs use a single committee that is legally obligated to be responsible for the interlocking oversight issues of biohazards, biotechnology, and dual use research at the local level.*

6. NIH has failed dismally to maintain the effective Institutional Biosafety Committee (IBC) system that is necessary for proper local oversight of research involving biological weapons agents. *Congress should strip NIH of its role overseeing IBCs and place that authority with a federal agency with regulatory power over IBCs at all US BSL-3 and BSL-4 laboratories, whether public or private, and federally funded or not.* This authority should not rest with an agency that makes research grants.

7. Americans will be safer from accidents and terrorism, and foreign nations will have greater confidence in our intent with biological weapons agent research (and thus be less likely to conduct secretive research themselves), if our program is a model of transparency and public accountability. This ethic needs to be instilled in our researchers. *Congress should act to improve the transparency and public accountability of the activities of our research* with steps including:
    a. Rolling back unwarranted secrecy at the CDC and elsewhere. There are mountains of federal biodefense records, currently unavailable to the public, that may be released in whole or nearly in their entirely without endangering the physical security of select agents;
    b. Improving the quality of disclosure of federal grants and research, particularly for DOD, DHS, and DOE by, for example, mandating the establishment of reliable, accurate, and accessible online databases of federal biodefense projects;
    c. Insisting upon vertical traceability from the lab bench to the top levels of federal agencies. When the government makes grants, the purpose, results, and safety and security oversight should be documented.
    d. Revisiting the FOIA Exemptions in the Bioterrorism Act of 2002, some of which are counterproductive, and as there are ways to release more information to the public without compromising the physical security of select agents.

7. The relationship between transparency and lab safety is a positive one. Americans in general, and local communities in particular, have a right to know what research is occurring in their midst and if labs are being operated safely and legally. US research will be more prudently and safely conducted when labs are accountable to the public. Labs can learn from each other and prevent accidents when they are discussed openly. *Congress should establish a mandatory and transparent national reporting system for accidents and near misses in BSL-3 and BSL-4 labs and this system should provide data at the local level.*

8. The CDC's interpretation of the Select Agent Rule's applicability to nucleic acids is unsafe and, arguably, a ticking time bomb. *Congress should instruct CDC to regulate nucleic acids that can be used to produce select agents or engineered organisms incorporating select agent characteristics.*

Mr. STUPAK. Thank you. Thank you all for your testimony. We will begin questioning, Dr. Gronvall. You indicated that your training was through an apprenticeship?

Ms. GRONVALL. Yes.

Mr. STUPAK. And you got to answer yes or no. I am sorry.

Ms. GRONVALL. Yes.

Mr. STUPAK. OK. With the proliferation of labs then, if you have to go through an apprenticeship, where are they getting the people to work in these labs?

Ms. GRONVALL. Well, I mean by working in laboratories as you are training to be a biological scientist, you work in a lab, you learn from the people who have worked there for more years and have more experience. So that is what I mean by mentor apprentice relationship.

Mr. STUPAK. OK. In your testimony, you described the proliferation of these level 3 and level 4 labs in U.S. and around the world. Are there too many high-containment labs in the U.S. in your opinion?

Ms. GRONVALL. I would say that we have so much research that needs to be accomplished, but that I really would have to know what is going on in the laboratories. I do not have enough information to answer that.

Mr. STUPAK. So in other words, needs assessment?

Msr. GRONVALL. I would like to know more to answer.

Mr. STUPAK. Are you aware of anyone ever doing a needs assessment?

Ms. GRONVALL. No.

Mr. STUPAK. OK. You make the point that no blame reporting may be a method of improving voluntary reporting and our ability to learn from mistakes. Is this the same type of systems that is in place for the nuclear industry? You mentioned airline industry but is that the model you are looking at?

Ms. GRONVALL. I think the main points of any model for reporting would just be to encourage reporting and to not punish people for reporting to make sure that there are incentives to report and that you are capturing as much experience as possible. So there are a number of industries, I think the chemical industry also has a reporting system like that.

Mr. STUPAK. But if they do not report, you have no problem with a punishment system then?

Ms. GRONVALL. I think where you want to go is that you want to make reporting to be the norm and not reporting to be something that you do not want to do.

Mr. STUPAK. OK. Dr. Pearson, let me ask you the same question. Are there too many high-containment labs in the United States?

Mr. PEARSON. I do not think without having a good needs assessment that you can answer that question.

Mr. STUPAK. And you are not aware of——

Mr. PEARSON. I have seen no evidence that there has been a good needs assessment done.

Mr. STUPAK. OK. What was that section you wanted us to look at, 351(a)(h)—the withholding?

Mr. PEARSON. Yes, it was passed in the Bioterrorism and Public Health Emergency Response Act of 2002.

Mr. STUPAK. OK. Mr. Hammond, you indicated there were two other Texas universities that came forward since Texas A&M became public. Do you know if the CDC has done anything with those two other universities?

Mr. HAMMOND. No, sir. In part, that is why I drew attention to CDC's policy to immediately reject all Freedom of Information Act requests. In the past, in addition to the two universities in Texas that reported, we have uncovered numerous additional incidents in other States that required reporting or appear to require reporting and we cannot obtain any documentation to determine whether or not they were, in fact, reported and whether or not CDC acted on the reports.

Mr. STUPAK. Have you then turned that information over to CDC, your Sunshine Project?

Mr. HAMMOND. I've made the information public in forums where CDC personnel—that are involved in the select agent program.

Mr. STUPAK. OK. After I want you to share that with the committee staff if you would. Those are the two universities, we will get to the bottom of it. You state in your testimony that the BSL lab expansion has gone "far beyond what is prudent and necessary." What is your estimate then of what is prudent and necessary here in the United States?

Mr. HAMMOND. I believe that a certain answer requires the needs assessment, however, my judgment based upon my experience is that we would be safer and could accomplish our national needs in biodefense if our program were perhaps a fifth or even smaller than what we have right now. That would imply a much smaller number of new labs. I believe that following the history of offensive biological weapons programs, following what happened in 2001 and expansion of our biodefense program was merited and that, logically, there should have been additional labs built to deal with revitalizing our biodefense program but we went considerably too far. So something on the order of a fifth is my estimation.

Mr. STUPAK. This committee has asked for a needs assessment too from CDC and they claim there is one out there but no one has ever seen it.

Mr. HAMMOND. I believe that.

Mr. STUPAK. You mentioned private corporate labs, Mr. Hammond, as being unaccounted for in the Government's oversight of the labs 3 and 4. What would you like to see done there on the private lab?

Mr. HAMMOND. One of the things that my organization has done in the past several years to look at the institutional biosafety committee system that is managed by the NIH Office of Biotechnology Activities. And compliance there is only required for institutions that are presently receiving NIH funding for recombinant DNA for genetic engineering research. I took a look at private sector compliance and found that out of the top 20 biotech companies, only about two are in compliance. I think that clearly the guidelines for recombinant DNA should be made a matter of law as should compliance with the BMBL and that should be applied to all laboratories, not simply those that are currently federally funded.

Mr. STUPAK. Thanks. My time is up but as I indicated in my opening statement, we will be sending our staff to look at some of these overseas labs. We are just as concerned. We want to get a hold of you or have you get a hold of us on what—because you are connected with Europe too you said. There is a Sunshine Project there?

Mr. HAMMOND. Yes, sir.

Mr. STUPAK. OK. We may want to get some suggestions on what labs you think we ought to look at, both secure and not so secure. Mr. Burgess for questions.

Mr. BURGESS. Thank you. Mr. Hammond, just let me be sure that I understand correctly. You are advocating 80 percent reduction on available laboratory capacity from where we are right now?

Mr. HAMMOND. No, sir. What I said was that I believe that a biodefense program that is approximately a fifth or perhaps even less of our present size would be able to adequately address our national security needs. And because there would be fewer people handling these agents and fewer laboratories, it would make us safer in the sense that there would be less opportunity for diversion of select agents. I am not advocating for any of the existing infrastructure, major infrastructure, to disappear. Rather this is with respect to the expansion.

Mr. BURGESS. So the expansion should be reduced by 80 percent. Are these expansion plans that currently exist? I guess what I am asking is—conducted the needs assessment that Chairman Stupak has asked CDC for. Do you have data that you can share with this committee about how you have arrived at those figures?

Mr. HAMMOND. My statement was with respect to the program as a whole, not with respect to a laboratory, the fifth comment. Not with respect to laboratories in particular. With laboratories, I believe that do need the needs assessment. But it is my judgment, having spent now a number of years in very intense interaction with practically every laboratory that handles these agents in the US, particularly outside of the Government sector, that that scale reduction would be appropriate and would make us, in fact, safer.

Mr. BURGESS. Let me ask you this because you raise a point in your written testimony that is significant about the building of an infectious agent out of its component parts, the nucleic acid issue. And if I understand your writing correctly, the CDC, in fact, has a loophole that would allow such a constructive infectious agent, say if someone was building the 1918 flu, had one nucleic acid change, that then is no longer an agent that falls on the select list, is that correct?

Mr. HAMMOND. That is correct, sir, in effect. The select agent rule in the plain language of the rule would appear to encompass these complimentary DNAs or these types of genetic constructs that you refer to. However, it appears that CDC has chosen to only consider those that are themselves infectious to be covered by the rule. And what this enables is for a person to possess, basically, all of the components that are needed to produce a select agent, even in a period of a few hours without being registered under the rule.

Mr. BURGESS. Mr. Chairman, I would like for it to be clarified to the committee, is this a rule that is been developed within the agency? Do they need legislative help to close the loophole? I would like for the committee staff to explore this so we know. This does not sound like a good idea and I think if we have learned nothing else today, this may be one of those things that we ought to try to immediately correct because it does sound like a significant defect. But I think I would also argue that we may need more lab space rather than less. But I do agree with you that the more people you have involved in a project, particularly when it is new and you are finding your way, the more people that are involved in a project, there is the greater potential for human error. Mr. Hammond, I got to tell you, I am from Texas. I have never heard of your group before. Where do you get your funding?

Mr. HAMMOND. In the way that most non-governmental organizations do. I receive contributions from individuals and I raise funding from foundations.

Mr. BURGESS. Can you supply to this committee a list of your major donors?

Mr. HAMMOND. I would be happy to, sir, but certainly I have a policy. I mean, the Sunshine Project engages in criticizing others on transparency issues, so certainly I would be more than happy to answer any question you have with respect to my organization.

Mr. BURGESS. You anticipated my question. I would ask the committee to make that generally available to members of the committee. And then I just have to ask you this. At the bottom, just before the table at the bottom of the first page, you reference the Sunshine Project, the Margaret Race of the SETI Institute. What does that acronym stand for?

Mr. HAMMOND. It is a NASA-funded institute that has to——

Mr. BURGESS. Is that the Search for Extra Terrestrial——

Mr. HAMMOND. Yes, Extra Terrestrial Intelligence.

Mr. BURGESS. OK.

Mr. HAMMOND. If I may, the interest there is that—and it can be corrected if I misspeak but the interest there is that the Government, NASA, has a long-term interest in potentially constructing a level 4 laboratory in the event that they return samples from Mars and so, therefore, NASA is interested in—it has funded work at the SETI Institution to keep track of issues related to biosafety level 4 labs.

Mr. BURGESS. As I recall, this group out of Berkeley was the one that connected personal computers across the country to evaluate whether there were meaningful signals coming from outer space. Do I remember that correctly?

Mr. HAMMOND. Sir, I honestly do not know but I do not believe so.

Mr. BURGESS. OK, I just had to ask. Mr. Chairman, if I may just ask Dr. Pearson a question. Your concept of the large oversight organization, is that generally accepted by other scientists who work in this area? If we were to take a poll of scientists who work on these problems, they would be enthusiastically supportive of you, moderately supportive of you or recoil in horror? Where would they fall on that metaphysical scale?

Mr. PEARSON. I think that you are asking a very good question. Certainly, it's a concept that has raised a lot of controversy and concern in the science community. We have an advisory board right now that is trying to look exactly at this question of what kind of oversight should be implemented on a national level. It is certainly an ongoing discussion. I think the question here is not whether or not we should have national oversight. The debate is over what that oversight should look like.

Mr. BURGESS. Mr. Chairman, I would just reference tab 22 in the binder you provided for us. There is some concern that too much movement too quickly in this arena will, in fact, stymie safety and have the adverse affect on safety that we all seek. So again, I do urge a little bit of caution when we get to the business of writing legislation. I do hope you will let the minority participate in whatever legislative comes out of these hearings and I will yield back the balance of my time.

Mr. STUPAK. Thank you, gentlemen. You mention national security. We invited the Department of Homeland Security to assist us in answering some of these questions and I was surprised and displeased, to say at the least, that they refused to show up, even though they are responsible for Homeland Security. So they declined our invitation but there will be more work to be done. Concludes questions. We got votes on the floor, so I am going to excuse this panel. I thank them for coming. Before you leave, one more question. Plum Island up in New York, we have a level 4 lab there, level 3, and they want to shut that one down and move it to the mainland. I think they do mostly foot-and-mouth disease there. Good idea, bad idea? Any comments. EHS does, that is why we are still to answer the question but go ahead. Mr. Hammond, I will go right down the line.

Mr. HAMMOND. My comment would be that it is not entirely clear to me at all that, in fact, Plum Island will be closed if the National Bio and Agro-Defense Facility is constructed. Among my recommendations was that Congress consider terminating the project to construct the National Bio and Agro-Defense Facility.

Mr. STUPAK. Right.

Mr. HAMMOND. Which would possibly imply that Plum Island would remain open, which is, I believe, may happen anyway.

Mr. STUPAK. Plum Island is one of the few places where no one lives there, it is just the lab is the only thing on Plum Island. That is why it makes sense I think. Dr. Pearson, anything on Plum Island or no opinion?

Mr. PEARSON. I am sorry, say that again.

Mr. STUPAK. Plum Island, should they close it?

Mr. PEARSON. Sure.

Mr. STUPAK. Move it to the mainland?

Mr. PEARSON. I think that with the case of Plum Island you have a 50-year old facility that clearly either needs to be replaced on Plum Island or replaced somewhere else. The issue with moving it to the mainland, I think the primary issue given the agents it is going to work with is, again, one of what happens if an agent gets out. If it is working with FMD and you plunk it down in the middle of cattle territory, is that a significant concern. So that is one thing. That is why it has been on Plum Island. It is simply an issue of do we have the oversight levels safe enough at that. The only other issue that I would raise and this, again, gets back to the needs assessment, I do believe that there is a need for a facility like Plum Island or NBAF. The issue is the new NBAF facility is going to be three times the size of Plum Island. So the question is, is it being scoped out in the right way. And that is where the needs assessment needs to come in. I believe DHS has at least done some needs assessment on that. I have not seen it and the committee might want to look at that.

Mr. STUPAK. Thank you. Dr. Gronvall?

Ms. GRONVALL. I think as far as Plum Island goes, the issue is really there are pluses and minuses for keeping it there or moving it. But the agents that they are going to be working with are select agents, the people who are involved go through the security procedure but there is no safety procedure and I think that is something that would need to be considered if you are going to keep it there or move it to make sure that the people are trained that are in the laboratory.

Mr. STUPAK. OK. Thank you and I will dismiss this panel and thank you for sharing your testimony with us today. That concludes all questioning. I want to thank the witnesses for coming today. I ask unanimous consent that the hearing will remain open for 30 days for additional questions for the record. With no objection, the record will remain open. I ask unanimous consent that the contents of our document binder be entered in the record and the staff have the chance to edit any sensitive documents prior to printing. No objection, the documents will be entered in the record. That concludes our hearing. This meeting of the subcommittee is adjourned.

[Whereupon, at 2:55 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

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MEETING REPORT

HIGH-CONTAINMENT BIODEFENSE RESEARCH LABORATORIES: MEETING REPORT AND CENTER RECOMMENDATIONS

Gigi Kwik Gronvall, Joe Fitzgerald, Allison Chamberlain, Thomas V. Inglesby, and Tara O'Toole

ON JULY 11, 2006, THE CENTER for Biosecurity of the University of Pittsburgh Medical Center (UPMC) convened an invitational meeting to discuss high-containment biodefense research in the United States. Our goal was to analyze whether and how the growing numbers of laboratories could be operated safely, productively, and with respect for the communities in which they are placed.

The group was composed of distinguished scientists and experts in biosafety, biosecurity, and public health and included proponents of the laboratories as well as those who oppose the recent expansion. Participants were not asked to reach consensus on the topics discussed; rather, the intention was to spur an open discussion of key issues related to high-containment laboratory research and to seek proposals for constructive actions. Meeting participants are listed in Appendix I. Individual comments were not for attribution, but some quotations that make a compelling case for particular actions are cited without attribution.

In this report, the Center for Biosecurity analyzes a number of critical issues related to high-containment laboratories and offers recommendations intended to improve their productivity, safety, and public engagement practices. These recommendations have been informed by pre- and post-meeting discussions with a range of experts, a survey of peer-reviewed literature, press reports, and discussions during the meeting on the issues summarized in this report. Our recommendations are not necessarily endorsed by the participants in the July 11 meeting.

BACKGROUND ON HIGH-CONTAINMENT BIOLOGICAL LABORATORIES

Laboratory biological research in the U.S. can be categorized by the safety level at which it is performed. The four safety levels are termed Biosafety Level (or BSL) 1 through 4. They are described in detail at the National Institutes of Health (NIH) website: http://www3.niaid.nih.gov/Biodefense/Public/Biolab.htm.[1] For the purposes of this report, high-containment biological research refers to work performed in the two highest levels, BSL-3 and BSL-4. BSL-3 laboratories are used to study biological agents that are potentially lethal and transmissible by the aerosol route and require special safety design features, such as sealed windows and specialized ventilation systems. BSL-4 laboratories are typically used to study lethal agents for which no vaccine or therapy is available. They incorporate the BSL-3 laboratory safety features, plus additional safety features such as full-body suits ventilated by life support systems.[2] In general, necessary biosafety precautions are dictated by the specifics of a biological experiment. Additional safety protection can be added to any biosafety level, from BSL-1 to -4, depending on the needs of a specific experiment.

Gigi Kwik Gronvall, PhD, is a Senior Associate; Joe Fitzgerald, MPH, is a Senior Associate; Allison Chamberlain is an Analyst; Thomas V. Inglesby, MD, is COO and Deputy Director; and Tara O'Toole, MD, MPH, is CEO and Director; all are at the Center for Biosecurity of the University of Pittsburgh Medical Center, Baltimore, Maryland.

A few years ago, only a handful of laboratories in the world operated at BSL-4, the highest level of containment. In the coming years, BSL-4 capacity will be expanded at least tenfold in the U.S., as laboratories currently under construction begin operations (see Figure 1 for a world map of BSL-4 laboratories, and Table 1 for a list of planned and operational BSL-4 laboratories).

A 2005 National Institutes of Health (NIH) survey estimates that there are currently 277 BSL-3 laboratories in the U.S.[3] The number may be higher: A 2005 Department of Homeland Security (DHS) and Department of Health and Human Services (HHS) report estimates that there are more than 600 BSL-3 laboratories in the U.S.[4] More BSL-3 laboratories are being built specifically for biodefense research, principally funded by the National Institute of Allergy and Infectious Diseases (NIAID) within the NIH (see Table 2 for a list of planned biodefense BSL-3 laboratories funded by NIAID).

The rapid expansion of high-containment laboratories has raised a number of policy issues, such as the adequacy of existing biosafety and biosecurity measures, personnel training in biosafety, transparency of laboratory policies and research directions, and the rationale justifying the BSL-3 and BSL-4 laboratory expansion. Additionally, public protests have occurred in many of the laboratory locations, raising the question of how the public should be involved in decision-making processes related to the labs, both in the siting process and once they are operational. Protests may have diminished some universities' success in receiving federal funding to build a high-containment laboratory.[5,6] In addition, public protests against the siting of the Boston University National Biocontainment Laboratory eventually led to citywide regulations on research activities and practice.[7]

Our meeting focused on these policy issues as they relate to high-containment laboratories in the U.S. However, we recognize that high-containment laboratory expansion is an international phenomenon. For example, in Southeast Asia, newly constructed BSL-3 laboratories are projected to become operational in 2006: in India (16 new laboratories), Thailand (5), Indonesia (2), Bangladesh (1), and Myanmar (1).[8] Our premise is that processes that make U.S. labs safer, more productive, and more transparent to the public will be helpful to laboratories and communities elsewhere in the world.

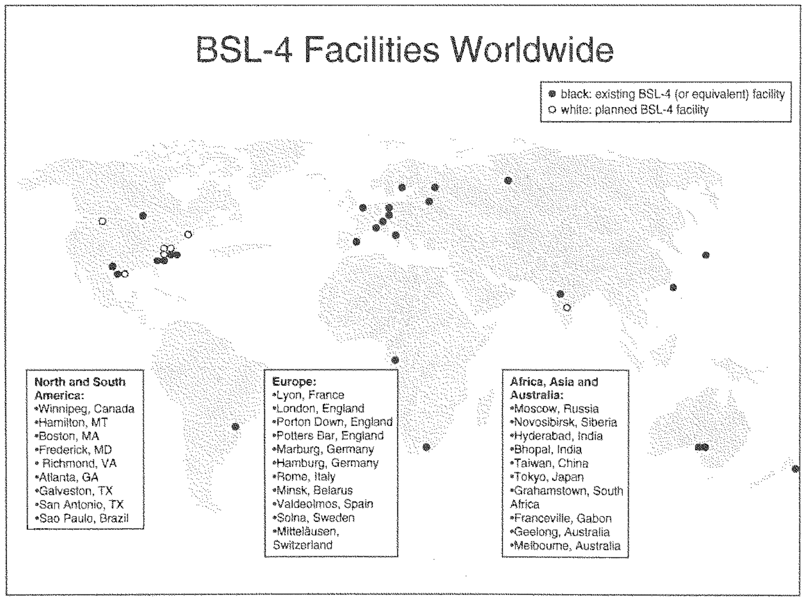

Figure 1. BSL-4 Facilities Worldwide

Table 1. BSL-4 Laboratories in the United States

Institution	Name of the Laboratory	Funds Allocated	Operational Status	Other Information
Centers for Disease Control and Prevention (Atlanta, GA)	CDC Special Pathogens Branch, Emerging Infectious Diseases Laboratory http://www.cdc.gov/ncidod/dvrd/spb/mnpages/whoweare.htm#what	$214 million to complete the Emerging Infectious Diseases Laboratory in October 2005[26]	New facility opened in 2005; prior lab opened in 1988[26]	
USAMRIID (Ft. Detrick, MD)	http://www.usamriid.army.mil/	$6 million upgrade to BSL-4 facilities in 2005; expansions projected to begin in 2006	1969; estimated completion date for upgrades is 2012[27]	
Southwest Foundation for Biomedical Research (San Antonio, TX)	BSL-4 Laboratory, Department of Virology and Immunology http://www.sfbr.org/pages/virology_index.php	As of 2005, endowment exceeds $80 million,[28] 70% funded by competitive peer-reviewed NIH grants, 12% private endowments.	Gloveboxes since the 1970s;[29] went to full biocontainment in 1999; opened in March 2000[30]	Conducts classified research; also has a national primate research center.[30] Serves as part of the BSL-4 Core of the NIAID Western Regional Center of Excellence in Biodefense.[31]
University of Texas Medical Branch (Galveston, TX)	UTMB Robert E. Shope, MD, BSL-4 Laboratory http://www.utmb.edu/CBEID/safety.shtml	$15.5 million[32]	June 2004[32]	Serves as part of the BSL-4 Core of the NIAID Western Regional Center of Excellence in Biodefense.[31]
Georgia State University (Atlanta, GA)	Viral Immunology Center http://www.cas.gsu.edu/units/default.aspx?unit=biotech&section=viral	NIH grants,[33] National Center for Research Resources (NCRR)	operational	
Virginia Commonwealth University (Richmond, VA)	Virginia Division of Consolidated Laboratory Services (DCLS) http://dcls.dgs.state.va.us/	$63 million to complete BSL-4 facilities building[34]	operational	
Department of Homeland Security (Ft. Detrick, MD)	National Biodefense Analysis and Countermeasures Center (NBACC) http://www.dhs.gov/xres/labs/gc_1166211221830.shtm	$128 million appropriated over FY2003–2005; estimated construction cost $141 million[35]	Broke ground June 2006; planned opening in 2008[38]	Governed by DHS Science and Technology Directorate; will conduct bioforensics and biological threat characterization.[36] The NBACC facility will provide biocontainment laboratory space for the National Bioforensic Analysis Center (NBFAC) and the Biological Threat Characterization Center (BTCC).[37]
National Institute of Allergy and Infectious Diseases (Hamilton, MT)	Rocky Mountain Laboratory (RML) Integrated Research Facility http://www3.niaid.nih.gov/about/organization/dir/rml/integrated ResearchFacility.htm	$66.5 million budgeted by Congress[38]	Construction began in 2004; slated for occupancy in 2007[39]	
National Institute of Allergy and Infectious Diseases and University of TX Medical Branch (Galveston, TX)	Galveston National Biocontainment Laboratory http://www.utmb.edu/GNL/faqs/3.shtml	Total anticipated cost: $167 million ($110 million fonded by NIH; UTMB to provide remainder) Estimated annual operating costs: $20 million+[40]	Projected opening date: June 2008[41]	To study anthrax, plague, hemorrhagic fevers (such as Ebola), typhus, West Nile virus, influenza, drug-resistant TB, etc.[42]
NIAID and Boston University (Boston, MA)	BU National Center for Emerging Infectious Diseases and Biodefense http://www.bu.edu/neidl/	$178 million ($128 million by NIAID)[43]	Expected construction completion date: 2008[44]	
National Institute of Allergy and Infectious Diseases (Fort Detrick, MD)	NIAID Integrated Research Facility at Fort Detrick http://www.niaid.nih.gov/factsheets/detrick_qa.htm	$105 million budgeted[45]	Estimated completion date: summer 2008[27]	

(continued)

Table 2. NIAID-funded Regional Biocontainment Laboratories (BSL-3)

Institution	Name of the Laboratory	Funds Allocated	Operational Status	Other Information
Colorado State University (Fort Collins, CO)	Regional Biocontainment Laboratory http://ghrc.colostate.edu/index.asp[47]	$22.1 million for construction of the building,[46] $16 million from NIAID[47]	Estimated completion: August 2008[47]	This site will also hold the new CDC $80 million Division of Vector-Borne Infectious Diseases, and the Regional Center of Excellence for Biodefense and Emerging Infectious Diseases.[48]
Duke University Medical Center (Durham, NC)	Global Health Research Building (GHRB) http://humanvaccine.duke.edu/modules/home/index.php?id=1	$20 million for construction:[49] $12 million from NIAID specifically for the RBL; $4 million from Duke	Estimated completion: 2006[50]	Will also house the federally funded $45 million Regional Center of Excellence for Emerging Infections and Biodefense (SERCEB), a consortium of which Duke is a member.[49]
George Mason University (Fairfax, VA)	George Mason University Biomedical Research Laboratory http://brl.gmu.edu/	$42 million in total: $25 million from NIAID; $15.3 million in matching funds from GMU; $2.5 million from the state[51]	Estimated completion: 2009[52]	Administered by the National Center for Biodefense and Infectious Diseases (NCBID) at George Mason University[51]
Tufts University, Cummings School of Veterinary Medicine (Grafton, MA)	Regional Biosafety Laboratory-New England (RBL-NE) http://www.tufts.edu/vet/rbl/	$20.8 million in total: $15.6 million from NIAID; $5.2 million from Tufts[53]	Estimated completion: 2009[53]	
Tulane National Primate Research Center (Covington, LA)	Regional Biocontainment Laboratory http://www.tulane.edu	Total project cost: $20 million;[54] $13.6 from NIAID[55]	Estimated completion: 2006[56]	
University of Alabama at Birmingham School of Medicine	Southeast Biosafety Laboratory Alabama (SEBLAB) http://main.uab.edu/show.asp?durki=61656	Total cost $22.3 million:[57] $15.9 million from NIAID;[58] $5 million from state;[57] $1.4 million from UAB[57]	Estimated completion: late 2007[57]	Southern Research Institute is a partner of University of Alabama in the operation of the laboratory.[59]
University of Chicago (Chicago, IL)	The Ricketts Laboratory http://www.htrl.uchicago.edu/	$31 million to build;[60] $25 million from NIAID[61,62]	March 2008[63]	Will also support the Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research, a consortium of research institutions funded by NIAID.
University of Hawaii at Manoa	Pacific Regional Biocontainment Laboratory http://www.hawaii.edu/	$37.5 million total; $25 million from NIAID;[64] $12.5 million from the state[65]	Construction begins in 2008; estimated completion: 2010[65]	
University of Louisville (Louisville, KY)	The Center for Predictive Medicine http://www.louisville.edu/community/biosafetylab/	$34.6 million total; $22 million from NIAID; $12.6 million from the university[66]	April 2009[66]	
University of Medicine and Dentistry of New Jersey (Newark, NJ)	New Jersey Medical School Center for Infectious Disease Research—RBL http://www.umdnj.edu/	$27.8 total; $20.9 million from NIAID;[67] $6.9 million from UMDNJ[68]	Construction to be completed in June 2008[69]	
University of Missouri–Columbia College of Veterinary Medicine	University of Missouri–Columbia Regional Biocontainment Laboratory http://www.rbl.missouri.edu	$16.5 million total; $12 million from NIAID[70]	Construction to be completed 2007[70]	
University of Pittsburgh (Pittsburgh, PA)	The Regional Biocontainment Laboratory at the Bioscience Tower III (BST3) http://www.pitt.edu/	$17.5M grant from NIAID specifically for the RBL[71]	Completed	BST3 will cost $205.5 million in total, and will house other research laboratories in addition to the RBL.[72]
University of Tennessee Health Science Center (Memphis, TN)	University of Tennessee Health Science Center Regional Biocontainment Laboratory http://www.utmem.edu/	$25 million total; $17.7 million from NIAID; $7.3 million from UTHSC[73]	2008[73]	

BIOSAFETY TRAINING

More people will soon be working in high-containment laboratories than ever before. For example, the Boston University National Biocontainment Laboratory will create an estimated 600 jobs,[9] and the not-yet-sited National Bio and Agro-Defense Facility may employ more than 300 researchers, technicians, and support staff.[10] Not all of these new employees will work in high-containment conditions, but it is widely agreed that the influx will strain the current national capacity for biosafety training.

Most research institutions require that all laboratory workers take a short class in biosafety principles. For workers in high-containment laboratories, advanced biosafety is usually taught within a mentor-apprentice relationship. Generally, as trainees improve, they move to higher levels of containment and independence. While there are some training programs available to supplement on-the-job experience (e.g., the Center for Public Health Preparedness and Research program at Emory University[11]), they are insufficient to build the workforce of researchers, technicians, and biosafety professionals needed to make the newly developed high-containment labs productive and safe.

Biosafety training entails more than learning to operate safety equipment, such as the full-body suit worn in many BSL-4 laboratories. Working safely with pathogens requires sound judgment, informed mostly by technical training and experience. As one meeting participant said, "I fear that some of our researchers believe that the engineering controls will provide their safety. And yet . . . it's the procedural controls and the practices of biosafety within the laboratory, regardless of what kind of building you're in, that are going to be the most critical in maintaining good safety." This was demonstrated in the SARS laboratory accidents that occurred in Singapore, China, and Taiwan, which were thought to have been caused not by equipment failure but by human error.[12–15]

Safety procedures for working with biological pathogens are more complicated and contextual than those for more quantifiable risks, such as radiation. Biological experimentation holds risks that change depending on the details of an experiment. Thus, each experiment requires a separate analysis of potential risks to determine appropriate research procedures. For example, an experiment that could normally be performed at a low biocontainment level may need increased biosafety protections if the researcher is immunocompromised, or if a large volume of infectious material is being handled. Likewise, a procedure that was always conducted at BSL-4 may be performed at BSL-3 if a vaccine becomes available that can protect the laboratory worker. A good biosafety officer can help a researcher determine the best biosafety procedures and practices for these laboratory-specific, experiment-specific decisions, so that the laboratory remains productive and safe. Unfortunately, as one meeting participant said, "I don't know of any program in the country right now that is really focusing attention on building that body of biosafety professionals that we need." One exemplary training program for biosafety officers, the National Biosafety and Biocontainment Training Program (NBBTP),[16] only graduates one or two biosafety professionals per year.

The diverse research backgrounds of the scientists now entering work on pathogens also increases the need for safety training in high containment. As one meeting participant said, "We're going to have all of these researchers and PIs who have crossed out 'plant' on their grants and written in 'anthrax' and have gotten funded."* The causative agent of anthrax can be worked on in a variety of biosafety levels, but the point is that many researchers will be working on potentially lethal organisms for the first time. Participation by scientists with diverse scientific backgrounds can be a positive development for research in new directions in a field and is the norm for scientific discovery. For example, when funding for HIV/AIDS research became available in the 1980s, researchers who had never previously worked with an infectious disease poured into the field. Nonetheless, for many researchers beginning to work with dangerous pathogens, the change in safety culture and safety practices will be serious. In many other areas of biological research, it is more important to protect the experiment from being contaminated by bacteria or viruses in the air than to protect the researcher from the experiment. Scientists coming from these low-risk fields into high-containment research will not be accustomed to the risks of infection and will need additional training. There also may be scientists coming from outside the biological sciences, from such areas as physics and chemistry, who may need additional training. One meeting participant remarked that there are "engineers . . . coming into [biodefense research] now through synthetic biology . . . who don't think of things as being self-replicating. And they are treating their experimental substrates as if they are not self-replicating."

The workforce that is needed to make the high-containment laboratories productive and safe is not yet in place. To develop the workforce, NIH should first assess how many people will require training for work in the high-containment laboratories, and develop and fund training programs that can supplement on-the-job training. Biosafety professionals with experience in laboratory research will be needed to provide training for and consultations with the researchers. Now that the Pandemic and All Hazards Preparedness Act (S. 3678) has been enacted, the National Science Advisory Board for Biosecurity (NSABB),[17] an advisory board to the Secretary of HHS on life science issues, may be directed to give their advice on "a core curriculum and training requirements for workers in maximum biological laboratories."[18] The diverse perspectives and backgrounds of NSABB members will be useful in establishing biosafety training standards on which to base on-the-job training.

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*Bacillus anthracis, the causative agent for anthrax disease, is usually worked on in BSL-2 facilities, although it can be worked with at varying BSLs. However, the point remains that new biodefense researchers may be unused to working with lethal pathogens.

Ultimately, it is the laboratory director's responsibility to ensure that all laboratory personnel "demonstrate high proficiency in standard microbiological practices and techniques," as stated in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidebook, published by the Centers for Disease Control and Prevention (CDC) and NIH.[2] But relying solely on the mentor-apprentice tradition of training for biosafety will not be sufficient to train the influx of high-containment scientists and technicians. Developing core competencies and standards will be useful in order to conserve mentors' valuable time and abilities.

Center for Biosecurity Recommendation #1:

> Biosafety training programs need to be expanded to accommodare researchers entering high-containment biological laboratory research. HHS should perform a needs assessment for training laboratory workers and biosafety officers at high-containment facilities. HHS should develop standardized core competencies for safety training of workers and scientists, to increase the efficiency of the current mentor-apprentice tradition.

INFORMATION EXCHANGE BETWEEN LABORATORIES

The implementation of the Select Agent Rule[19] and concerns about legal liability have inadvertently become major barriers that are preventing high-containment laboratory researchers from learning from each other's experiences in biosafety practices.

Individuals who wish to work with a wide range of pathogens must abide by the Select Agent Rule, as defined by 45 CFR 72. Under the rule, HHS and the U.S. Department of Agriculture (USDA) keep lists of pathogens that require select agent clearance. The rule regulates the possession, use, and transfer of those agents; imposes security requirements for the facility in which the work will be performed; requires inspections; and can impose criminal and civil penalties on those who do not adhere to the law.

Security risk assessments are administered to individuals who work with select agents by the Department of Justice (DOJ), a process that is renewed every five years. Once cleared, an individual is allowed to work with a specific biological agent, but only within a specific laboratory. The specificity of this clearance procedure inhibits the practical exchange of safety-related information and techniques between high-containment laboratory researchers, by preventing, for example, a technician in one laboratory from demonstrating techniques in another laboratory without going through a separate lengthy clearance process.

In addition to the clearance barriers that prevent timely sharing of practical safety techniques, there is a perception that laboratories will be liable for accidents that occur to scientists who are visiting for training purposes. Whether or not these perceived concerns are real, they need to be examined in detail and addressed so that experienced scientists can more easily demonstrate techniques and safety procedures developed in one laboratory to another. This would speed up the process for new laboratories to become productive, and, more important, should enhance their safety.

As one meeting participant remarked, "As someone who has actually taken a lab hot, I have experience with how you train people. . . . There were no guidelines. There was no checklist. There was nothing. And we reached out to CDC. We reached out to Fort Detrick. We got as much help as they could give. After 9/11, they couldn't give us as much help as they could give before. And so, now that we've been hot, and we've worked with animals, and we've had to do it on our own with just commonsense rules, people are now coming to us and saying, will you help train us? Well, now our lawyers are saying, no, you can't let any nonemployee into the lab. I think what we need to do as a group is to try to develop a policy that says we will assist each other in this training procedure." NIH and CDC should work to make this possible.

Center for Biosecurity Recommendation #2:

> High-containment laboratories need to share lessons learned. Mechanisms should be put in place to enable and encourage interlaboratory training and information exchange. This requires modifying the Select Agent Rule to accelerate the process of safety and technical training, and examining whether perceived barriers, such as legal liability concerns, actually prevent information and safety sharing.

LEARNING FROM BIOSAFETY MISTAKES

In the decades of research performed at BSL-4, with hundreds of practitioners, there have been only a handful of laboratory-acquired infections reported. In U.S. BSL-4 laboratories, there have been no reported cases of secondary transmission, which is defined as the transmission of a laboratory-acquired infection from one person to another. The meeting participants who have experience in BSL-4 conditions did not feel that the reporting of accidents is a problem. As one participant said, "There isn't anybody in there that wants to catch their experiment, for the simple reason [they] don't want to die."

The record of laboratory-acquired infections at lower levels of containment is less clear, but the meeting participants thought it was much less laudable. In fact, no one knows precisely how many accidents occur at the lower containment levels, including diagnostic clinical laboratories, because laboratory-acquired infections are generally not severe and are not reported. Illnesses may not even be recognized as having been acquired in the laboratory. The Select Agent Rule requires reporting of infections of all select agents, whether they occur at BSL-2, -3, or -4 laboratories. However, there are many infectious diseases that are not on the select agent list, for which there are anecdotes of laboratory-acquired infections but few documented reports.

Research institutions are typically required by NIH grants to report any serious accidents or research-acquired infections, but there is no regulatory requirement to report and no penalty for not reporting. The Occupational Safety and Health Administration (OSHA) within the Department of Labor has illness notification requirements,[20] but the threshold for reporting is considered to be several infected individuals. The lack of reporting has consequences beyond the individual affected laboratory. Unless someone chooses to write a scientific paper documenting the incident, lessons learned from the experience are generally not reflected in new editions of the BMBL (the biosafety guidebook written by NIH and CDC), so that procedures can be analyzed and future accidents perhaps avoided.

There are several explanations for the lack of reporting. Generally, there is a disincentive to report acquired infections and other mishaps at research institutions, because negative publicity or the scrutiny from a granting agency may adversely affect future research funding. In addition, when a scientist acquires an infection in the laboratory, it is almost always his or her fault, and neither the scientist nor the laboratory wishes to advertise the mistake. For example, the mistake may have resulted from a researcher being inattentive, tired, or distracted by other tasks; perhaps the worker had done the procedure many times before and became inured to the risks. Finally, even if reporting were required, once a worker gets infected and becomes ill, he or she becomes a patient—and thus is afforded certain protections and privacy.

These barriers need to be cleared so biosafety can be enhanced through shared learning from mistakes, and also so the public may be reassured that accidents are thoroughly examined and contained. One possible analogous mechanism discussed by meeting participants is the reporting system used for aviation incidents, administered by the National Transportation Safety Board and the Federal Aviation Administration (FAA).[21,22] Mistakes are analyzed and learned from, but they are not attributed to individuals (except when mistakes result from criminal actions, such as drunkenness).

If a similar system were applied to high-containment laboratories, publicizing the names of those involved would be unnecessary; the participants in the meeting agreed that personal anonymity would bolster incentives to report. Participants in the meeting disagreed, however, about whether the laboratory's research institution could remain anonymous as well after an accident or a near-miss. Some felt that institutional anonymity may be necessary to get robust reporting (the FAA does not include the names of the airlines in their incident reports). As one participant said, "If people are whacked on the head when they report anything going wrong, whether it was an honest mistake or an error or a piece of equipment failing, they will find ways not to report. . . . So the more transparency you have, the fewer penalties you must have." But as another meeting participant pointed out, "If I live in Seattle and the [researchers] in Seattle that are fooling around with 1918 [influenza] constructs start screwing up and dropping things in the lab, . . . to have a national reporting system that doesn't reflect or doesn't inform anybody in and around Seattle . . . is a total letdown to the people."

Center for Biosecurity Recommendation #3:

A system should be established by NIH or CDC to provide an analysis of mistakes and near-misses in high-containment laboratories. Institutional anonymity may be necessary in order for overall safety goals to be achieved; however, procedures need to define thresholds and mechanisms for reporting if mistakes pose a danger to the community surrounding the laboratory.

PUBLIC ENGAGEMENT

High-containment laboratories have become increasingly controversial because of highly publicized laboratory errors, such as the missteps of Boston University in handling tularemia infections in three laboratory workers.[23] The issue of public engagement was the most important to our meeting participants but generated the least consensus regarding appropriate actions.

NIAID has a great deal of information about all of the biodefense laboratories on its website, including a collective rationale for why the laboratories are being built.[1] However, engagement with communities where the laboratories are actually being built is typically handled by the institution proposing the laboratory. Thus, the strategies and outcomes of public engagement, as well as the transparency of laboratory operations to the public, have varied considerably. Public resistance was experienced during efforts to build facilities in Boston, in Davis, California, in Hamilton, Montana, and in

Seattle, whereas generally positive support was achieved for the Galveston laboratory administered by the University of Texas Medical Branch. In the end, both the Davis and Seattle facilities were not built, in part due to public opposition.

Laboratories that have been accepted by their communities have by and large instituted procedures that not only encourage active reporting of problems but also keep the community informed about operations. Studies have been written contrasting successes and failures of various high-containment laboratories; this work should be expanded, learned from, and implemented for all laboratories.[5,24] Individual laboratories bear final responsibility for their relationships with their communities, but there should be a more aggressive and proactive federal effort to standardize public engagement and transparency of operations and to direct funds to this purpose.

A public engagement program needs to address the concerns that have surfaced in siting high-containment laboratories. A fundamental error made by some proponents of these labs is to conflate all protests against the laboratories as a lack of understanding of science (R. Lofstedt, personal communication, July 11, 2006). In the media reports that describe the controversies about the labs, a number of specific concerns appear repeatedly: People fear that weapons will be worked on in the labs, and that the Biological Weapons Convention will be violated; that diseases will be released into the public; that the government could not manage an accident response (as was the case in the aftermath of Hurricane Katrina); and that the lab would make the area a target for terrorism. Some who protest the labs are not against the lab per se, but feel that the location chosen for the lab is unacceptable, or that the lab would not provide jobs or other benefits to locals. Some feel that giving more people access to select agents will lead to an increased chance of accidents or, even worse, an increased risk of terrorism. Each of these issues needs to be actively addressed both by HHS and NIAID and by the institution sponsoring the laboratory.

The larger question of whether these laboratories are justified at all also needs to be addressed by focusing on the specific roles of individual laboratories and how they fit into the overall biodefense strategy. The community that surrounds the laboratory should know the strategic importance of their laboratory and why its existence is necessary. The NSABB, in their charge to provide the HHS Secretary with "periodic evaluations of maximum containment biological laboratory capacity nationwide and assessments of the future needs for increased laboratory capacity," should specifically address the individual role each laboratory should play in the overall federal biosecurity strategy.[18]

For many years, there was a clear shortage of biological high-containment laboratories.[25] Now, after funds have been committed and construction has begun, there should be greater clarity about whether there is enough capacity, the right kind of capacity (e.g., sufficient animal facilities or laboratories that can meet FDA requirements for Good Laboratory Practices), or an excess. Defining the roles of specific laboratories in terms of a larger biodefense strategy will not only help to justify their existence to their neighbors and funders; it will also help to design safety programs for the laboratories and to ensure that the laboratories are doing important, nonduplicative research in the future.

Center for Biosecurity Recommendation #4:

> Public engagement should be a priority for all laboratories, and federal funds should be made available specifically for that purpose. As part of a proactive public engagement program, the need for individual high-containment laboratories in the context of the overall U.S. biodefense strategy should be clearly articulated to the public by the federal government and the laboratories themselves.

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Appendix 1: Participants in the July 11, 2006, High-Containment Biodefense Research Forum

Kevin Anderson, PhD, Deputy Director (Acting), National Biodefense Analysis Countermeasures Center (NBACC), Science & Technology Directorate, Department of Homeland Security
Allison Chamberlain, Analyst, Center for Biosecurity of UPMC
Joseph Fitzgerald, MHS, MPH, Senior Associate, Center for Biosecurity of UPMC
Michele S. Garfinkel, PhD, Policy Analyst, The Venter Institute
Gigi Kwik Gronvall, PhD, Senior Associate, Center for Biosecurity of UPMC
Edward Hammond, Director, The Sunshine Project
Thomas V. Inglesby, MD, Chief Operating Officer and Deputy Director, Center for Biosecurity of UPMC
Peter Jahrling, PhD, Chief Scientist, National Institute of Allergies & Infectious Diseases
Julie Fischer, PhD, Senior Associate, The Henry L. Stimson Center
Ragnar E. Lofstedt, PhD, Director, King's Centre for Risk Management, School of Social Science and Public Policy, King's College
Stephanie S. Loranger, PhD, Senior Program Officer, Global Health and Security Initiative, Nuclear Threat Initiative
Tara O'Toole, MD, MPH, Chief Executive Officer and Director, Center for Biosecurity of UPMC
David Ozonoff, MD, MPH, Professor of Environmental Health, Chair Emeritus, Department of Environmental Health, Boston University School of Public Health
Jean Patterson, PhD, Chairman, Department of Virology & Immunology, Southwest Foundation for Biomedical Research
Margaret S. Race, PhD, Principal Investigator, SETI Institute
Jonathan Y. Richmond, PhD, Jonathan Richmond & Associates, Inc.
Reynolds M. Salerno, PhD, Manager, International Biological Threat Reduction, Sandia National Laboratories
Martin L. Sanders, PhD, CBSP, Deputy Director, Office of Health and Safety, Centers for Disease Control & Prevention
Michael Stebbins, PhD, Director of Biology Policy, Federation of American Scientists

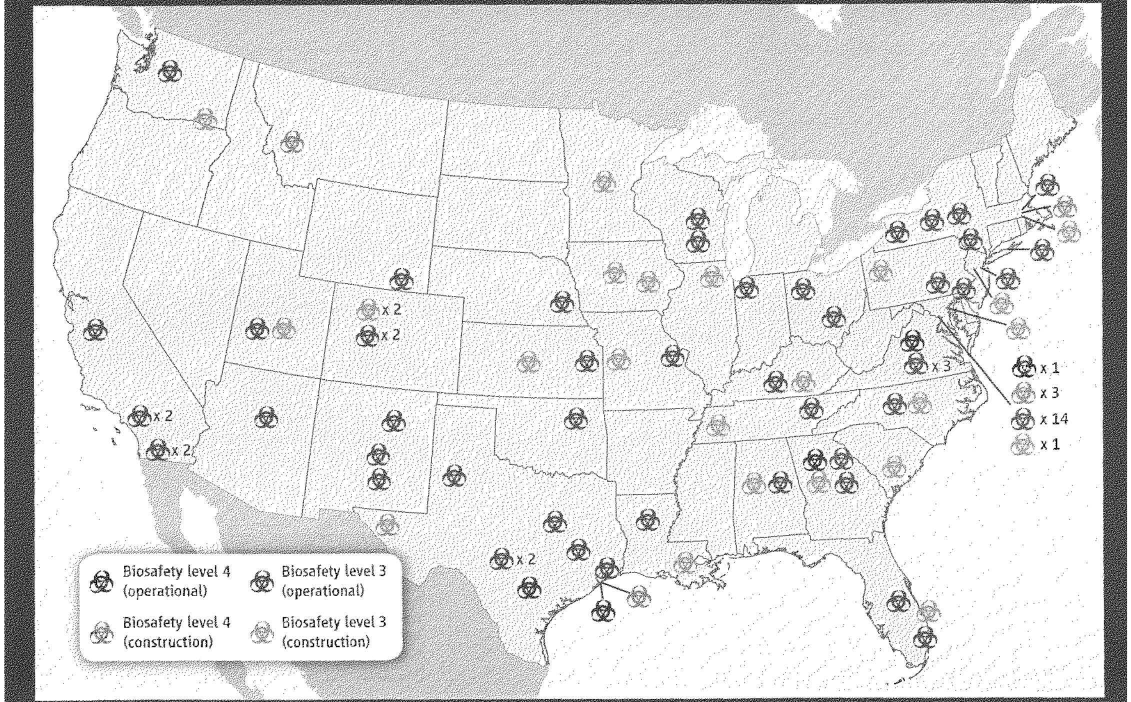
Ex. #	Description	Date
1	Subcommittee on Oversight and Investigations Witness List	10/04/07
2	O&I Hearing Memo; subject: "Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States."	10/03/07
3	Chart and Legend, "Federally-funded BSL 3 and 4 Labs."	02/20/06
	Centers for Disease Control and Prevention (CDC) - Texas A&M University Correspondence	
4	Facility Inspection Report: Texas A&M University	03/09/04
5	Facility Inspection Report: Texas A&M University	03/25/05
6	Facility Inspection Report: Texas A&M University	04/18/06
7	Facility Inspection Report: Texas A&M University	05/04/07
8	Suspension of Select Agent Work: Texas A&M University	06/30/07
9	Facility Inspection Report: Texas A&M University	08/31/07
10	Brucella Exposure Field Report	06/17/06
	Energy & Commerce Committee Plum Island Disease Center Correspondence	
11	Letter to Charles F. Conner, Acting Secretary, U.S. Department of Agriculture.	09/20/07
12	Letter to Michael Chertoff, Secretary, U.S. Department of Homeland Security.	09/20/07
	Miscellaneous Documents	
13	CDC Form 3 Incident Reports	08/28/07
14	HHS and DHS Report to Congress, subject: "Project BioShield Report on Biocontainment Facilities."	January 2007
15	United Kingdom's Health and Safety Executive report, subject: "Final Report on Potential Breaches of Biosecurity at the Pirbright Site 2007."	2007
16	United Kingdom's Department for Environment, Food, and Rural Affairs webpage article, "Foot and Mouth Disease (Introduction)."	
17	Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science journal article, subject: "Billions for Biodefense: Federal Agency Biodefense Funding, FY2006-FY2007."	2006
18	List of Select Agents, source: Biosafety in Molecular Biology and Biomedical Laboratories journal and "Foreign Animal Diseases," "The Gray Book" at www.vet.uga.edu.	
	News Articles	

19	The Economist, subject: "Own Goal (Foot-and-Mouth Disease)."	08/09/07
20	Sunday Telegraph article by Richard Gray, subject: "How Safe is Biosafe?"	08/14/07
21	Science Magazine article, subject: "Reports Blame Animal Health Lab in Foot-and-Mouth Whodunit."	09/14/07
22	Science Magazine article, subject: "Accidents Spur a Closer Look at Risks at Biodefense Labs."	09/28/07
23	Associated Press article by Larry Margasak, subject: "Mishandling of Germs on Rise at U.S. Labs."	09/02/07
24	Associated Press article, subject: "U.S. Labs Mishandling Deadly Germs."	09/02/07
25	The Atlanta Journal-Constitution article, subject: "Congress Probes Labs' Handling of Germs…"	09/03/07
26	Los Angeles Times article by Jia-Rui Chong, subject: "Research into Potent Bioagents Increases the Risk…"	09/03/07
27	The Wall Street Journal article, subject: "Lab Toxin Mishaps Rise."	09/03/07

[*Editor's note*: Exhibit Nos. 4-10 and 14, 15 are on file in the committee office.]

Exhibit No. 3

Federally-funded BSL 3 and 4 Labs


x 2
x 2
x 2
x 2
x 3
x 2
x 1
x 3
x 14
x 1
Biosafety level 4 (operational)
Biosafety level 3 (operational)
Biosafety level 4 (construction)
Biosafety level 3 (construction)

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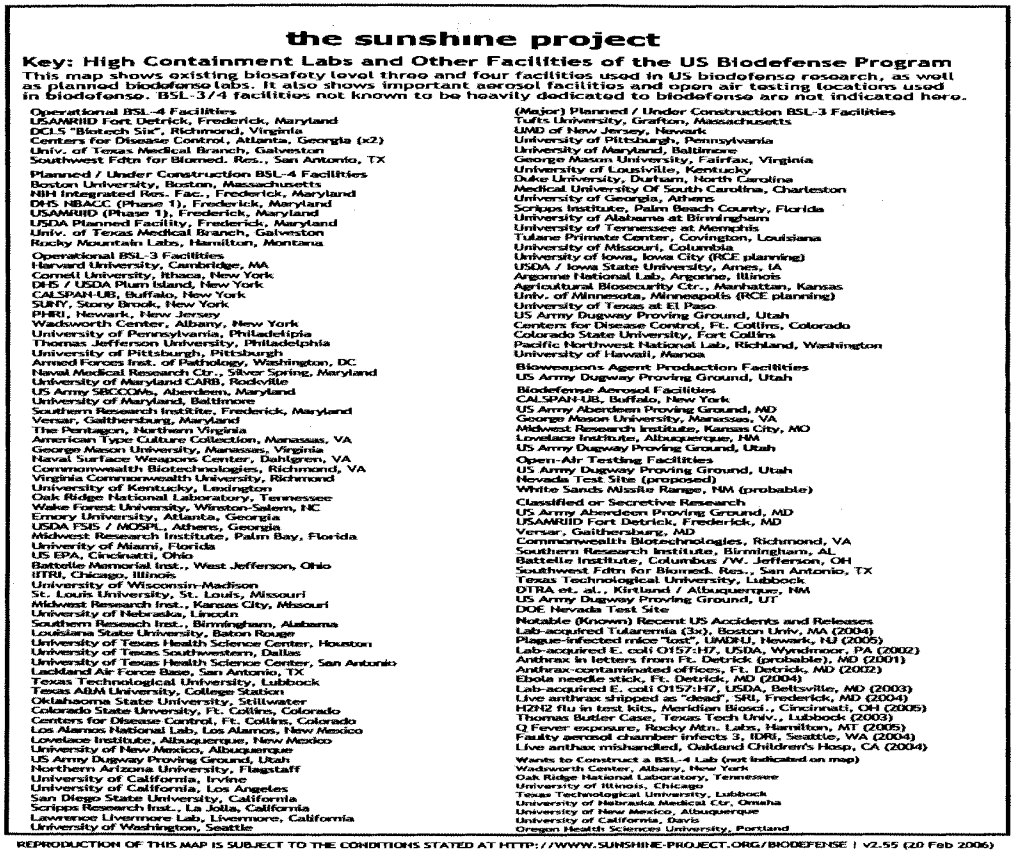

the sunshine project

Key: High Containment Labs and Other Facilities of the US Biodefense Program

This map shows existing biosafety level three and four facilities used in US biodefense research, as well as planned biodefense labs. It also shows important aerosol facilities and open air testing locations used in biodefense. BSL-3/4 facilities not known to be heavily dedicated to biodefense are not indicated here.

Operational BSL-4 Facilities
USAMRIID Fort Detrick, Frederick, Maryland
DCLS "Biotech Six", Richmond, Virginia
Centers for Disease Control, Atlanta, Georgia (x2)
Univ. of Texas Medical Branch, Galveston
Southwest Fdtn for Biomed. Res., San Antonio, TX

Planned / Under Construction BSL-4 Facilities
Boston University, Boston, Massachusetts
NIH Integrated Res. Fac., Frederick, Maryland
DHS NBACC (Phase 1), Frederick, Maryland
USAMRIID (Phase 1), Frederick, Maryland
USDA Planned Facility, Frederick, Maryland
Univ. of Texas Medical Branch, Galveston
Rocky Mountain Labs, Hamilton, Montana

Operational BSL-3 Facilities
Harvard University, Cambridge, MA
Cornell University, Ithaca, New York
DHS / USDA Plum Island, New York
CALSPAN-UB, Buffalo, New York
SUNY, Stony Brook, New York
PHRI, Newark, New Jersey
Wadsworth Center, Albany, New York
University of Pennsylvania, Philadelipia
Thomas Jefferson University, Philadelphia
University of Pittsburgh, Pittsburgh
Armed Forces Inst. of Pathology, Washington, DC
Naval Medical Research Ctr., Silver Spring, Maryland
University of Maryland CARB, Rockville
US Army SBCCOMs, Aberdeen, Maryland
University of Maryland, Baltimore
Southern Research Institite, Frederick, Maryland
Versar, Gaithersburg, Maryland
The Pentagon, Northern Virginia
American Type Culture Collection, Manassas, VA
George Mason University, Manassas, Virginia
Naval Surface Weapons Center, Dahlgren, VA
Commonwealth Biotechnologies, Richmond, VA
Virginia Commonwealth University, Richmond
University of Kentucky, Lexington
Oak Ridge National Laboratory, Tennessee
Wake Forest University, Winston-Salem, NC
Emory University, Atlanta, Georgia
USDA FSIS / MOSPL, Athens, Georgia
Midwest Research Institute, Palm Bay, Florida
Univerity of Miami, Florida
US EPA, Cincinatti, Ohio
Battelle Memorial Inst., West Jefferson, Ohio
IITRI, Chicago, Illinois
University of Wisconsin-Madison
St. Louis University, St. Louis, Missouri
Midwest Research Inst., Kansas City, Missouri
University of Nebraska, Lincoln
Southern Reseach Inst., Birmingham, Alabama
Louisiana State University, Baton Rouge
University of Texas Health Science Center, Houston
University of Texas Southwestern, Dallas
University of Texas Health Science Center, San Antonio
Lackland Air Force Base, San Antonio, TX
Texas Technological University, Lubbock
Texas A&M University, College Station
Oklahoma State University, Stillwater
Colorado State Unversity, Ft. Collins, Colorado
Centers for Disease Control, Ft. Collins, Colorado
Los Alamos National Lab, Los Alamos, New Mexico
Lovelace Institute, Albuquerque, New Mexico
University of New Mexico, Albuquerque
US Army Dugway Proving Ground, Utah
Northern Arizona University, Flagstaff
University of California, Irvine
University of California, Los Angeles
San Diego State University, California
Scripps Research Inst., La Jolla, California
Lawrence Livermore Lab, Livermore, California
University of Washington, Seattle

(Major) Planned / Under Construction BSL-3 Facilities
Tufts University, Grafton, Massachusetts
UMD of New Jersey, Newark
University of Pittsburgh, Pennsylvania
University of Maryland, Baltimore
George Mason University, Fairfax, Virginia
University of Lousiville, Kentucky
Duke University, Durham, North Carolina
Medical University Of South Carolina, Charleston
University of Georgia, Athens
Scripps Institute, Palm Beach County, Florida
University of Alabama at Birmingham
University of Tennessee at Memphis
Tulane Primate Center, Covington, Louisiana
University of Missouri, Columbia
University of Iowa, Iowa City (RCE planning)
USDA / Iowa State University, Ames, IA
Argonne National Lab, Argonne, Illinois
Agricultural Biosecurity Ctr., Manhattan, Kansas
Univ. of Minnesota, Minneapolis (RCE planning)
University of Texas at El Paso
US Army Dugway Proving Ground, Utah
Centers for Disease Control, Ft. Collins, Colorado
Colorado State University, Fort Collins
Pacific Northwest National Lab, Richland, Washington
University of Hawaii, Manoa

Bioweapons Agent Production Facilities
US Army Dugway Proving Ground, Utah

Biodefense Aerosol Facilities
CALSPAN-UB, Buffalo, New York
US Army Aberdeen Proving Ground, MD
George Mason University, Manassas, VA
Midwest Research Institute, Kansas City, MO
Lovelace Institute, Albuquerque, NM
US Army Dugway Proving Ground, Utah

Open-Air Testing Facilities
US Army Dugway Proving Ground, Utah
Nevada Test Site (proposed)
White Sands Missile Range, NM (probable)

Classified or Secretive Research
US Army Aberdeen Proving Ground, MD
USAMRIID Fort Detrick, Frederick, MD
Versar, Gaithersburg, MD
Commonwealth Biotechnologies, Richmond, VA
Southern Research Institute, Birmingham, AL
Battelle Institute, Columbus /W. Jefferson, OH
Southwest Fdtn for Biomed. Res., San Antonio, TX
Texas Technological University, Lubbock
DTRA et. al., Kirtland / Albuquerque, NM
US Army Dugway Proving Ground, UT
DOE Nevada Test Site

Notable (Known) Recent US Accidents and Releases
Lab-acquired Tularemia (3x), Boston Univ, MA (2004)
Plague-infected mice "lost", UMDNJ, Newark, NJ (2005)
Lab-acquired E. coli O157:H7, USDA, Wyndmoor, PA (2002)
Anthrax in letters from Ft. Detrick (probable), MD (2001)
Anthrax-contaminated offices, Ft. Detrick, MD (2002)
Ebola needle stick, Ft. Detrick, MD (2004)
Lab-acquired E. coli O157:H7, USDA, Beltsville, MD (2003)
Live anthrax shipped as "dead", SRI, Frederick, MD (2004)
H2N2 flu in test kits, Meridian Biosci., Cincinnati, OH (2005)
Thomas Butler Case, Texas Tech Univ., Lubbock (2003)
Q Fever exposure, Rocky Mtn. Labs, Hamilton, MT (2005)
Faulty aerosol chamber infects 3, IDRI, Seattle, WA (2004)
Live anthax mishandled, Oakland Children's Hosp, CA (2004)

Wants to Construct a BSL-4 Lab (not indicated on map)
Wadsworth Center, Albany, New York
Oak Ridge National Laboratory, Tennessee
University of Illinois, Chicago
Texas Technological University, Lubbock
University of Nebraska Medical Ctr, Omaha
University of New Mexico, Albuquerque
University of California, Davis
Oregon Health Sciences University, Portland

REPRODUCTION OF THIS MAP IS SUBJECT TO THE CONDITIONS STATED AT HTTP://WWW.SUNSHINE-PROJECT.ORG/BIODEFENSE | v2.55 (20 Feb 2006)

Exhibit No. 11

HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, Jr., NEW JERSEY
BART GORDON, TENNESSEE
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
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DENNIS B. FITZGIBBONS, CHIEF OF STAFF
GREGG A. ROTHSCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
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MICHAEL C. BURGESS, TEXAS
MARSHA BLACKBURN, TENNESSEE

September 20, 2007

The Honorable Charles F. Conner
Acting Secretary
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250

Dear Acting Secretary Conner:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the management, operation, and activities of the Department of Homeland Security's (DHS's) Plum Island Animal Disease Center (PIADC), including the recent proposal by DHS to close the PIADC and relocate its operations to a new facility, to be called the National Bio and Agro-Defense Facility (NBAF). The Committee has jurisdiction over interstate and foreign commerce generally, public health and quarantine, biomedical programs and health protection in general, food safety, drug safety, environmental protection, and the homeland security-related aspects of the foregoing.

The Plum Island research facility has been in operation for more than 50 years, the majority of that time owned and managed by the U.S. Department of Agriculture (USDA). In June 2003, operational responsibility for the PIADC was transferred to DHS, while the research staff continued to be employed by USDA. It is the Committee's understanding that the majority of the research at Plum Island has been concentrated on foot-and-mouth disease (FMD), which, as you know, is highly contagious. Research has also been conducted on classical swine fever, African swine fever, and other diseases.

The PIADC was originally sited on Plum Island due to concerns that an accidental release of the extraordinarily hazardous viruses and other diseases handled at that facility would pose a serious threat to animal health and, in some cases, human health and the environment. The natural barrier of water surrounding the island, along with its remoteness at the far end of Long Island, New York, were perceived as, and have apparently been successful over the last 50 years, an effective buffer zone between Plum Island research and farming activities in the rest of the country.

There is no doubt that a release of FMD or swine fever could be devastating to the livestock industry in the United States. The 2001 outbreak of FMD in the United Kingdom resulted in the destruction of millions of cattle and sheep and cost more than $16 billion. The 2007 U.K. outbreak was identified and isolated almost immediately, so its economic effects were limited. This incident, however, illustrates how easily the disease can spread from a government research facility located in a farming community on the mainland of England.

We are concerned that inadequate consideration may have been given to the hazards of shutting down the Plum Island PIADC and transferring its operations—and the live virus stored there—to the interior of the United States. We are also concerned that the direct and indirect costs of this proposal may have not have been fully considered.

To aid in our investigation, please provide the following information and records:

1. Does USDA agree with the DHS proposal to close the Plum Island PIADC and transfer its operations elsewhere?

2. Please provide copies of all records, including memoranda, reports, studies, etc., dated January 1, 2002, or later, whether draft or final, discussing whether Plum Island should be closed and/or relocated.

3. Has an assessment been conducted that reviewed the need for the closure, expansion, or replacement of the PIADC? If so, please provide a copy.

4. Plum Island covers some 840 acres of land. If there is a need to expand the PIADC facilities at Plum Island, is there enough room at Plum Island to accommodate that expansion?

5. Please provide a detailed description of USDA's role in the planning, construction, and operation of the proposed NBAF.

6. The scientific research conducted at the Plum Island PIADC typically requires highly trained professionals. Please provide a list of researchers employed at the PIADC, with names omitted, showing the education level, field of expertise, and pay grade/compensation rate for each.

7. Closing the PIADC and transferring its functions to the new NBAF would require the transfer of the current research staff to the new location. Experience at other government laboratories shows that a large number of such personnel would be unable

or unwilling to relocate, thus causing a substantial loss in expertise and continuity of operations. Has USDA estimated the number of researchers who would be likely to refuse a transfer from Plum Island? Please provide copies of any such analysis.

8. Please provide copies of all records pertaining to the need for and cost of environmental cleanup at Plum Island.

9. How many people are employed by USDA at Plum Island?

10. Have any outside contractors been involved in proposing, analyzing, or planning the closing of the Plum Island PIADC or the establishment of the NBAF? If so, please provide their names and roles.

11. Please provide a description of all renovations and new construction carried out at Plum Island in the past 10 years. Please provide detailed cost data by year for each of the past 10 years on the cost of such renovations and new construction.

12. Classical swine fever and African swine fever could be devastating to the swine populations of the United States. Yet, apparently, swine fever research at Plum Island has been severely curtailed in recent years. Why has swine fever research at Plum Island been virtually eliminated? Please provide copies of all records since January 1, 1997, regarding the decision to reduce swine fever research at Plum Island.

13. Has USDA been contacted by members of the agricultural and livestock industries regarding the proposal to close Plum Island and transfer FMD and other livestock disease research to another facility in the United States? If so, please provide copies of all records pertaining to such contacts.

14. Under Federal law (7 USC 113a), no live virus of foot-and-mouth disease may be introduced for any purpose into any part of the mainland of the United States without the express permission of the Secretary of Agriculture, who must find that it is both necessary and in the public interest. Has the Secretary granted such permission at any time in the last 10 years? If so, please provide a list of all such instances.

15. Do you intend to grant permission for the transfer of live virus of foot-and-mouth disease from the PIADC to a new location on the mainland United States, if the PIADC is closed?

16. The PIADC includes a biosafety level 3 (BSL–3) laboratory. Please identify the types of research currently being performed in this BSL–3 laboratory and which have been performed at any time since January 1, 1997.

17. It is our understanding that DHS plans to construct a BSL–4 laboratory as part of the new NBAF. In your opinion, is a BSL–4 laboratory needed at either Plum Island or at the proposed NBAF to conduct research on plant and animal disease? Please provide copies of any analysis that has been performed on this issue.

Please deliver the requested information and records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, room 316 Ford House Office Building, no later than the close of business on October 2, 2007.

In responding to this request, please be advised that the terms "records" and "relating to" are defined in the attachment to this letter.

If you elect to assert a privilege or objection to the production of the foregoing records or information, please provide a privilege log fully identifying each record withheld and the legal basis asserted for withholding the record from a congressional committee of competent jurisdiction.

If you have any questions regarding this request, please contact us or have your staff contact John Arlington, Senior Investigative Counsel with the Committee on Energy and Commerce staff, at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

Exhibit No. 12

ONE HUNDRED TENTH CONGRESS
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

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JOHN SULLIVAN, OKLAHOMA
TIM MURPHY, PENNSYLVANIA
MICHAEL C. BURGESS, TEXAS
MARSHA BLACKBURN, TENNESSEE

September 20, 2007

The Honorable Michael Chertoff
Secretary
U.S. Department of Homeland Security
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20229

Dear Secretary Chertoff:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the management, operation, and activities of the Department of Homeland Security's (DHS) Plum Island Animal Disease Center (PIADC), including the recent proposal by DHS to close the PIADC and relocate its operations to a new facility, to be called the National Bio and Agro-Defense Facility (NBAF). The Committee has jurisdiction over interstate and foreign commerce generally, public health and quarantine, biomedical programs and health protection in general, food safety, drug safety, environmental protection, and the homeland security-related aspects of the foregoing.

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There is no doubt that a release of FMD or swine fever could be devastating to the livestock industry in the United States. The 2001 outbreak of FMD in the United Kingdom resulted in the destruction of millions of cattle and sheep, and cost more than $16 billion. The 2007 U.K. outbreak was identified and isolated almost immediately, so its economic effects were limited. It illustrates, however, how easily the disease can spread from a government research facility located in a farming community on the mainland of England.

We are concerned that inadequate consideration may have been given to the hazards of shutting down the Plum Island PIADC and transferring its operations—and the live virus stored there—to the interior of the United States. We are also concerned that the direct and indirect costs of this proposal may have not have been fully considered, including the environmental impact of closing Plum Island and building a new mainland facility.

To aid in our investigation, please provide the following information and records:

1. Why is DHS considering closing the Plum Island PIADC and transferring its operations elsewhere?

2. Please provide copies of all records, including memoranda, reports, studies, etc., dated January 1, 2002, or later, whether draft or final, discussing whether Plum Island should be closed and/or relocated.

3. Has an assessment been conducted that reviewed the need for the closure, expansion, or replacement of the PIADC? If so, please provide a copy.

4. Plum Island covers some 840 acres of land. If DHS has concluded that there is a need for a larger facility, please explain why 840 acres is not large enough to accommodate such expansion.

5. Please provide an estimate of the costs of each of the following: (a) closing the PIADC; (b) transferring PIADC personnel to a new facility; and (c) constructing the NBAF.

6. The scientific research conducted at the Plum Island PIADC typically requires highly trained professionals. Please provide a list of researchers employed at the PIADC, with names omitted, showing the education level, field of expertise, and pay grade/compensation rate for each.

7. Closing the PIADC and transferring its functions to the new NBAF would require the transfer of the current research staff to the new location. Experience at other Government laboratories shows that a large number of such personnel would be unable or unwilling to relocate, thus causing a substantial loss in expertise and continuity of operations. Has DHS estimated the number of researchers who would be likely to refuse a transfer from Plum Island? Please provide copies of any such analysis.

8. Has DHS or any other entity conducted an assessment of the nature and extent of any environmental cleanup that would be necessary following the closing of the PIADC? If so, what is the estimated cost of such cleanup?

9. Please provide copies of all records pertaining to the need for and cost of environmental cleanup at Plum Island.

10. How many people are employed at Plum Island? Of this number, please identify the number employed by DHS, USDA, or other entities.

11. Have any outside contractors been involved in proposing, analyzing, or planning the closing of the Plum Island PIADC or the establishment of the NBAF? If so, please provide their names and roles.

12. Please provide a description of all renovations and new construction carried out at Plum Island in the past 10 years. Please provide detailed cost data by year for each of the past 10 years on the cost of such renovations and new construction.

13. Classical swine fever and African swine fever could be devastating to the swine populations of the United States. Yet, apparently, swine fever research at Plum Island has been severely curtailed in recent years. Why has swine fever research at Plum Island been virtually eliminated? Please provide copies of all records since January 1, 2002, regarding the decision to reduce swine fever research at Plum Island.

14. Has DHS been contacted by members of the agricultural and livestock industries regarding the proposal to close Plum Island and transfer FMD and other livestock disease research to another facility in the United States? If so, please provide copies of all records pertaining to such contacts.

15. The PIADC includes a biosafety level 3 (BSL–3) laboratory. Please identify the types of research currently being performed in this BSL–3 laboratory and which have been performed at any time since January 1, 2002.

16. It is our understanding that DHS plans to construct a BSL–4 laboratory as part of the new NBAF.

    a. What specific pathogens does DHS intend to study at this new BSL–4 facility?

    b. Has a needs assessment been conducted for this proposed BSL–4 lab? If so, please provide a copy of the assessment.

c. Has DHS considered using existing, government-owned BSL–4 laboratories to conduct this research? If so, please provide copies of all records discussing this alternative.

d. What is the estimated cost of constructing a new BSL–4 laboratory as part of the NBAF? Please provide a copy of the most recent cost estimate.

Please deliver the requested information and records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, room 316 Ford House Office Building, no later than the close of business on Tuesday, October 2, 2007.

In responding to this request, please be advised that the terms "records" and "relating to" are defined in the attachment to this letter.

If you elect to assert a privilege or objection to the production of the foregoing records or information, please provide a privilege log fully identifying each record withheld and the legal basis asserted for withholding the record from a congressional committee of competent jurisdiction.

If you have any questions regarding this request, please contact us or have your staff contact John Arlington, Senior Investigative Counsel with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

Exhibit No. 13

Report Date	Type of Report	Entity	Entity Type	Select Agent/Toxin	Laboratory Biosafety Level	Summary	Status
3/3/2005	Loss	American Type Culture Collection	Commercial	*Brucella melitensis*	BSL-3	Discrepancy in shipment - 1 vial not shipped.	Closed
10/6/2005	Loss	American Type Culture Collection	Commercial	*Bacillus anthracis*	BSL-3	Discrepancy in shipment - 1 vial not shipped.	Referred to OIG
10/13/2005	Loss	American Type Culture Collection	Commercial	Venezuelan Equine Encephalitis virus	BSL-3	Discrepancy in shipment - 1 vial not shipped.	Closed
12/15/2004	Loss	American Type Culture Collection (receiver)*	Commercial	*Yersinia pestis*	BSL-3	Discrepancy in shipment - 1 vial not shipped.	Closed
8/15/2003	Loss	Armed Forces Institute of Pathology	Government - Federal	*Francisella tularensis & Yersinia pestis*	BSL-3	Loss in transit while importing select agents. Per FBI, packages discovered and incinerated in Belgium.	Closed
11/7/2006	Release	Armed Forces Institute of Pathology	Government - Federal	*Bacillus anthracis*	BSL-2	Unlikely exposure - Entity confirmed select agent was taken from BSL-3 lab to BSL-2 lab, but employees were using proper PPE.	Investigation ongoing
4/21/2004	Loss	Battelle Memorial Institute	Government - Federal	*Staphylococcal enterotoxin*	BSL-3	Shipped inactivated toxin.	Not a select agent
10/20/2005	Loss	Battelle Memorial Institute	Government - Federal	*Botulinum neurotoxin producing species of Clostridium*	BSL-3	Inventory discrepancy - individual failed to note container with select agent had been destroyed.	Closed
7/23/2007	Release	Battelle Memorial Institute	Government - Federal	Avian influenza virus	BSL-3	Potential exposure - needlestick with syringe containing select agent	USDA select agent - Referred to APHIS.
8/9/2007	Release	BD Diagnostics	Private	*Brucella abortus*	BSL2	Potential exposure to select agent when laboratorian failed to turn on autoclave.	Investigation ongoing
9/12/2006	Release	BioPort Corporation	Commercial	*Bacillus anthracis*	BSL-2	Potential exposure - employee cut arm with box cutter in a room that select agent work is performed.	Closed
9/19/2006	Release	BioPort Corporation	Commercial	*Bacillus anthracis*	ABSL-2	Potential exposure - lab worker bitten by infected guinea pig.	Closed
7/23/2007	Release	Bioqual	Private	Avian influenza virus	BSL3/ABSL-3	Potential exposure - employee bitten by ferret inoculated with select agent.	USDA select agent - Referred to APHIS.
7/18/2007	Loss	California Department of Health, Richmond	Government - Non Federal	Monkeypox virus	BSL-2	Possible loss of select agent.	Investigation ongoing
5/31/2007	Release	Centers for Disease Control and Prevention	Government - Federal	*Coxiella burnetii*	BSL-3	Unlikely exposure - airflow found to be reversed for BSL-3 lab. During the period of reversed airflow, the laboratory was unoccupied.	Investigation ongoing

Report Date	Type of Report	Entity	Entity Type	Select Agent/Toxin	Laboratory Biosafety Level	Summary	Status
10/28/2005	Loss	Centers for Disease Control and Prevention	Government - Federal	*Coxiella burnetii*	BSL-3	Inventory discrepancy - inventory reported as missing due to poor prior record-keeping.	Referred to OIG
12/15/2005	Loss	Commonwealth Biotechnologies, Inc.	Commercial	*Bacillus anthracis*	BSL-2	Discrepancy in shipment - incorrect number of vials was shipped by sender.	Closed
1/23/2004	Release	Division of Vector-Borne Infectious Diseases/NCID/CDC	Government - Federal	*Russian Spring & Summer Virus*	BSL-2	Unlikely exposure - collection from '40-50, vials labelled as RSSV, entity could not confirm viability.	Closed
11/9/2006	Release	DVBID/CDC	Government - Federal	*Yersinia pestis*	BSL-2	Unlikely exposure when laboratorian dropped two culture plates containing select agent (lid intact or plate face down).	Closed
3/2/2006	Release	DVBID/NCID/CDC	Government - Federal	Venezuelan Equine Encephalitis virus	BSL-3	Unlikely exposure - entity confirmed no exposure to select agent when plate containing select agent dropped to the floor (plate landed upside down)	Closed
11/23/2005	Loss	Focus Diagnostics, Inc.	Commercial	*Brucella suis & Brucella melitensis*	BSL-3	Inventory discrepancy - individual failed to note isolates that had been destroyed.	Closed
8/9/2004	Release	Georgia Public Health Laboratory	Government - Non Federal	*Brucella melitensis*	BSL-2	Laboratorian became ill after working with a diagnostic culture that was later identified as a select agent.	Closed
12/23/2004	Loss	Greer Laboratories, Inc. (sender)*	Commercial	*Yersinia pestis*	BSL-2	Discrepancy in shipment - 1 vial not shipped.	Closed
5/1/2007	Release	Kentucky, CHFS, DPH, DLS	Government - Non Federal	*Brucella melitensis*	BSL-3	Potential exposure - laboratorian working with diagnostic sample on benchtop.	Investigation ongoing
9/25/2006	Release	Lovelace Respiratory Research Institute	Academic	*Yersinia pestis*	ABSL-3	Potential exposure - animal infected with select agent bit laboratorian.	Follow-up compliance inspection to be scheduled to confirm procedures have been updated and proper safety plans are in place
11/13/2006	Release	Lovelace Respiratory Research Institute	Academic	Monkeypox virus	ABSL-3	Unlikely exposure when notebook was removed from lab where work was performed on select agent. The room had been decontaminated with Vaporized Hydrogen peroxide prior to removal.	Follow-up compliance inspection to be scheduled to confirm procedures have been updated and proper safety plans are in place

Report Date	Type of Report	Entity	Entity Type	Select Agent/Toxin	Laboratory Biosafety Level	Summary	Status
4/11/2007	Release	Lovelace Respiratory Research Institute	Academic	*Yersinia pestis*	ABSL-3	Potential exposure - laboratorian scratched by animal infected with select agent.	Follow-up compliance inspection to be scheduled to confirm procedures have been updated and proper safety plans are in place
5/30/2007	Release	Lovelace Respiratory Research Institute	Academic	*Bacillus anthracis*	ABSL-3	Potential exposure when notebooks were removed from lab where work was performed on select agent.	Investigation ongoing
6/26/2007	Release	Lovelace Respiratory Research Institute	Academic	*Bacillus anthracis* & Avian Influenza virus	ABSL-3	Potential exposure when notebooks were removed from lab where work was performed on select agent.	Investigation ongoing
8/28/2007	Release	Lovelace Respiratory Research Institute	Academic	*Yersinia pestis*	ABSL-3	Potential occupational exposure to select agent as a result of an employee being stuck by a broken scalpel blade	Investigation ongoing
5/17/2007	Loss	Mayo Clinic	Academic	*Coccidioides immitis*	BSL-3	Package shipped via FedEx and lost in transit	Investigation ongoing
3/6/2003	Loss	MDPH/BLS/State Laboratory Institute	Government - Non Federal	*Genomic material of Burkholderia mallei & Burkholderia pseudomallei*	BSL-3	Inventory discrepancy due to poor record-keeping.	Not a select agent
12/8/2004	Release	Medical College of Ohio	Academic	*Coccidioides immitis*	BSL-3	Laboratorian diagnosed with Cocciodioidomycosis. No exposure could be confirmed because the individual has been working with agent for nearly 20 years.	Closed
9/30/2005	Release	Medical College of Ohio at Toledo	Academic	*Coccidioides immitis*	BSL-3	Potential exposure of 1 individual when broken vial containing select agent was discovered in centrifuge.	Closed
3/21/2007	Loss	Medical College of Wisconsin, Inc.	Academic	*Francisella tularensis*	BSL-3	Inventory discrepancy - entity determined vials were accidentally autoclaved	Investigation ongoing
3/11/2004	Loss	Midwest Research Institute	Commercial	*Bacillus anthracis*	BSL-3	Discrepancy in shipment - 2 vials not shipped.	Closed
9/7/2004	Loss	Midwest Research Institute	Commercial	*Yersinia pestis, Bacillus anthracis, and Botulinum neurotoxins*	BSL-3	Shipment held for 5 days due to hurricane.	Closed
9/22/2005	Release	Midwest Research Institute	Commercial	*Bacillus anthracis*	BSL-2	Potential exposure - 2 laboratorians opened package that contained leaking tubes on open bench.	Referred to OIG

Report Date	Type of Report	Entity	Entity Type	Select Agent/Toxin	Laboratory Biosafety Level	Summary	Status
12/7/2005	Release	Midwest Research Institute	Commercial	*Bacillus anthracis*	BSL-2	Potential exposure - laboratorians opened package that contained unknown liquid.	Closed
12/6/2004	Loss	Midwest Research Institute	Commercial	*Francisella tularensis*	BSL-3	Discrepancy in shipment - 1 vial not shipped.	Closed
3/18/2004	Loss	MIT Lincoln Laboratory	Academic	*Bacillus anthracis*	BSL-2	Discrepancy in shipment - shipped empty box.	Closed
11/13/2006	Release	National Animal Disease Center	Government - Federal	*Brucella suis*	BSL-3	Potential release due to leakage problem with collection tank that may have contained select agent.	Closed
12/8/2006	Release	National Animal Disease Center	Government - Federal	*Brucella suis*	BSL-3	Potential exposure - Employee cut finger while repairing pipe that may have contained select agent.	Closed
12/22/2006	Release	National Animal Disease Center	Government - Federal	*Brucella suis*	BSL-3	Potential release due to leakage problem with collection tank that may have contained select agent.	Closed
1/11/2007	Release	National Animal Disease Center	Government - Federal	*Brucella suis*	ABSL-3	Potential exposure - employee bitten by pig infected with select agent.	Closed
6/4/2007	Release	National Animal Disease Center	Government - Federal	*Brucella abortus*	ABSL-3	Potential exposure - laboratorian scratched by broken rib during necropsy.	Investigation ongoing
7/2/2007	Release	National Animal Disease Center	Government - Federal	*Brucella suis*	ABSL-3	Potential exposure - needlestick with syringe containing select agent during necropsy	Investigation ongoing
4/25/2006	Loss	New Jersey State Department of Health and Senior Services	Government - Non Federal	*Bacillus anthracis*	BSL-3	Inventory discrepancy due to poor record-keeping.	Closed
5/18/2005	Loss	Northern Arizona University	Academic	*Bacillus anthracis*	BSL-2	Discrepancy in shipment - 1 vial not shipped.	Closed
7/25/2007	Release	Oakland County Health Division Lab	Government - Non Federal	*Bacillus anthracis*	BSL-2	Potential exposure - employee stabbed by broken capillary tube that may have been used for PCR testing for Bacillus anthracis.	Investigation ongoing
12/18/2006	Loss	Oklahoma State University	Academic	*Francisella tularensis*	ABSL-3	Inventory discrepancy noted in number of mice held for incineration after completing experiment. Entity determined that employee left dead mouse inside cage and that it was autoclaved and destroyed with the bedding.	Follow-up compliance inspection to be scheduled to confirm procedures have been updated and proper security plans are in place
9/26/2006	Release	Parkway Regional Medical Center	Commercial	*Burkholderia pseudomallei*	BSL-2	Potential exposure - 3 laboratorians exposed while sniffing plates that contained select agents.	Closed

Report Date	Type of Report	Entity	Entity Type	Select Agent/Toxin	Laboratory Biosafety Level	Summary	Status
8/31/2005	Loss	Public Health Research Institute	Academic	*Yersinia pestis*	ABSL-3	Inventory discrepancy - entity could not account for 3 infected mice. It was determined that the mice were cannibalized by other mice in the cage or buried under the bedding and autoclaved by mistake by the animal care staff.	Referred to OIG
2/16/2005	Release	Rocky Mountain Laboratories, NIAID, NIH	Government - Federal	*Coxiella burnetii (Nine mile strain)*	BSL-2	Potential exposure - individuals possibly expose when culture fluid discovered in bottom of centrifuge.	Not a select agent
6/17/2004	Release	Southern Research Institute	Commercial	*Bacillus anthracis*	BSL-3	Potential exposure - individuals possible inadvertent exposure to select agents that they believed were non-viable.	Referred to OIG
5/16/2005	Release	St. Louis University	Academic	Monkeypox virus	ABSL-3	Unlikely exposure - infected lung tissue spattered on disposable lab gown of a laboratorian vaccinated against the select agent.	Closed
8/7/2007	Release	St. Louis University	Academic	Monkeypox virus	ABSL-3	Potential exposure - needlestick with syringe containing select agent	Investigation ongoing
12/22/2006	Loss	Texas A&M University	Academic	*Coxiella burnetii*	ABSL-3	Inventory discrepancy - infected mouse discovered missing. Entity determined mouse was likely autoclaved with bedding material and disposed.	Referred to OIG
4/11/2007	Release	Texas A&M University	Academic	*Brucella melitensis*	BSL-3	Researcher became ill as a result of improper decontamination procedures.	Referred to OIG
4/24/2007	Release	Texas A&M University	Academic	*Coxiella burnetii*	BSL-3	Potential exposure - entity reported three individuals w/ elevated Q fever titers.	Investigation ongoing
5/18/2007	Release	Texas A&M University	Academic	*Coxiella burnetii*	BSL-3	Potential exposure - entity reported one individual w/ elevated Q fever titers.	Investigation ongoing
7/9/2007	Release	Texas A&M University	Academic	*Coxiella burnetii*	BSL-3	Potential exposure - entity reported four individuals w/ elevated Q fever titers.	Investigation ongoing
7/9/2007	Release	Texas A&M University	Academic	*Coxiella burnetii*	BSL-3	Potential exposure - entity reported one individual w/ elevated Q fever titers.	Investigation ongoing
7/9/2007	Release	Texas A&M University	Academic	*Coxiella burnetii*	BSL-3	Potential exposure - entity reported one individual w/ elevated Q fever titers.	Investigation ongoing

Report Date	Type of Report	Entity	Entity Type	Select Agent/Toxin	Laboratory Biosafety Level	Summary	Status
7/31/2007	Loss	Texas A&M University	Academic	*Brucella abortus*	BSL-3	Three vials discovered missing during inspection of entity.	Investigation ongoing
7/16/2007	Release	The University of Chicago	Academic	*Bacillus anthracis*	BSL-3	Potential exposure - needlestick with syringe containing select agent.	Investigation ongoing
5/10/2007	Release	The University of Iowa	Academic	*Francisella tularensis*	BSL-3	Potential exposure - One individual working with suspension of bacterial growth on open bench that was later identified as a select agent.	Investigation ongoing
12/21/2004	Release	Trustees of Boston University	Academic	*Francisella tularensis*	ABSL-3	3 laboratorians became ill after working with the wild-type select agent instead of what the laboratorians believed as the excluded select agent.	Closed
4/10/2006	Release	Tufts Cummings School of Veterinary Medicine	Academic	*Botulinum neurotoxins*	BSL-2	Potential exposure of 5 individuals when broken vial containing select agent was discovered in centrifuge.	Closed
2/18/2004	Release	United States Army Medical Research Institute of Infectious Diseases	Government - Federal	*Ebola virus*	ABSL-4	Potential exposure - Needle grazed laboratorian while injecting antibodies into infected mice.	Closed
4/1/2005	Release	United States Army Medical Research Institute of Infectious Diseases	Government - Federal	*Bacillus anthracis (excluded strain)*	BSL-3	Potential exposure - BSC fan was turned off while work was being performed in BSC and nasal swab confirmed exposure to excluded strain.	Not a select agent
6/29/2007	Release	United States Army Medical Research Institute of Infectious Diseases	Government - Federal	*Bacillus anthracis*	BSL-3	Potential exposure - environmental surveillance indicated presence of select agent on freezer handle, light switch, and shoes in the hot side of the change room	Closed
5/16/2006	Release	University of California San Diego	Academic	*Brucella abortus*	BSL-3	Potential exposure of nine individuals working with select agent on benchtop.	Investigation ongoing
7/27/2007	Release	University of California, Davis	Academic	*Brucella abortus*	ABSL-3	Potential exposure - needlestick with syringe containing select agent.	Investigation ongoing
5/25/2006	Release	University of Kentucky	Academic	*Yersinia pestis*	BSL-3	Potential exposure to laboratorian after opening an autoclave bag containing select agent that had not been decontaminated.	Closed
5/9/2007	Release	University of Kentucky	Academic	*Yersinia pestis*	BSL-3	Potential exposure - autoclave bag leaked.	Investigation ongoing

Report Date	Type of Report	Entity	Entity Type	Select Agent/Toxin	Laboratory Biosafety Level	Summary	Status
3/14/2006	Release	University of Louisiana at Lafayette	Academic	*Brucella abortus*	BSL-3	Potential exposure to select agent when laboratorian failed to turn on autoclave.	Closed
8/25/2006	Loss	University of Medicine and Dentistry of New Jersey	Academic	*Burkholderia mallei*	BSL-3	Inventory discrepancy - during inventory reconciliation, entity determined that the vial was never filled.	Follow-up compliance inspection to be scheduled to confirm procedures have been updated and proper security plans are in place
9/15/2006	Loss	University of Medicine and Dentistry of New Jersey	Academic	*Bacillus anthracis*	BSL-3	Inventory discrepancy - entity determined that the vial was left unfilled from initial spore stock preparation.	Follow-up compliance inspection to be scheduled to confirm procedures have been updated and proper security plans are in place
8/15/2007	Release	University of Mississippi Medical Center	Academic	*Bacillus anthracis*	BSL-3	Potential exposure - Flask containing select agent broke and spilled on floor.	Investigation ongoing
3/11/2003	Loss	University of New Mexico	Academic	*Staphylococcal enterotoxin*	ABSL-3	Inventory discrepancy due to poor record-keeping.	Not a select agent
7/23/2007	Release	University of New Mexico	Academic	*Francisella tularensis*	ABSL-3	Potential exposure - employee bitten by rat inoculated with select agent.	Investigation ongoing
9/14/2004	Release	University of North Carolina at Chapel Hill	Academic	*Venezuelan Equine Encephalitis virus*	BSL-3	Laboratorian had high rise in anti-VEE virus titer. No occupational exposure confirmed.	Closed
10/15/2004	Release	University of North Carolina at Chapel Hill	Academic	*Venezuelan Equine Encephalitis virus*	BSL-3	Addendum to previous report on 9/14/07 which reported laboratorian had high rise in anti-VEE virus titer. No occupational exposure confirmed.	Closed
5/7/2007	Release	University of North Carolina at Chapel Hill	Academic	*Venezuelan Equine Encephalitis virus*	BSL-3	Potential exposure - dirty mouse cage dropped inside BSL3 suite.	Investigation ongoing
3/5/2003	Loss	University of Scranton	Academic	*Genomic material of Brucella abortus, Brucella melitensis, and Brucella suis*	BSL-3	Inventory discrepancy due to poor record-keeping.	Not a select agent
7/19/2007	Release	University of South Alabama	Academic	*Ricksettia prowazekii*	BSL-3	Potential exposure - employee dropped plate while removing from incubator, splashed in lab coat, pants, shoes.	Investigation ongoing
3/30/2006	Loss	University of South Carolina	Academic	*Bacillus anthracis*	BSL-2	Inventory discrepancy - inventory reported as missing due to poor record-keeping.	Referred to OIG

Report Date	Type of Report	Entity	Entity Type	Select Agent/Toxin	Laboratory Biosafety Level	Summary	Status
4/20/2007	Release	University of Texas at San Antonio	Academic	*Francisella tularensis*	BSL-3	Unlikely exposure - facilities personnel entered BSL3 lab without proper personal protective equipment. No select agent work was being performed.	Investigation ongoing
5/8/2007	Release	University of Texas Health Science Center at Houston	Academic	*Bacillus anthracis*	BSL-3	Potential exposure - four individuals possibly expose when culture fluid discovered in bottom of centrifuge.	Investigation ongoing
8/11/2006	Release	University of Virginia	Academic	*Francisella tularensis*	BSL-3	Potential exposure when tube containing select agent in shaker appeared to be cracked.	Closed
4/11/2007	Release	University of Virginia	Academic	*Francisella tularensis*	BSL-3	Potential exposure - Needlestick with syringe that had been in contact with mice inoculated with select agent.	Investigation ongoing
8/7/2006	Release	University of Wisconsin - Madison	Academic	*Brucella melitensis*	BSL-3	Potential exposure to 2 individuals when cap on tube containing select agent came off in shaker.	Closed
3/24/2005	Loss	University of Wisconsin-Madison	Academic	*Botulinum neurotoxin producing species of Clostridium*	BSL-2	Discrepancy in shipment - 1 vial not shipped.	Closed
5/17/2004	Release	Veterans Affairs San Diego Healthcare System	Government - Federal	*Coccidioides immitis*	BSL-3	No release occurred because the power outage occurred in room after the laboratorians performing necropsy of infected mice and culture tissue inside a BSC that never lost power.	Closed
4/27/2005	Release	Walter Reed Army Institute of Research/Naval Medical Research Center	Government - Federal	*Yersinia pestis*	BSL-3	Potential exposure - laboratorian dropped agar plate containing select agent outside BSC.	Closed
5/2/2005	Release	Walter Reed Army Institute of Research/Naval Medical Research Center	Government - Federal	*Yersinia pestis*	BSL-3	Potential exposure - laboratorian cut finger during animal necropsy.	Closed
1/2/2006	Release	Walter Reed Army Institute of Research/Naval Medical Research Center	Government - Federal	*Brucella abortus, Brucella melitensis, Brucella suis, and Yersinia pestis*	BSL-3	Unlikely exposure - water supply broke inside lab causing a floor. Water samples were negative.	Closed

Report Date	Type of Report	Entity	Entity Type	Select Agent/Toxin	Laboratory Biosafety Level	Summary	Status
5/13/2004	Loss	Walter Reed Army Med	Government - Federal	*Francisella tularensis (LVS)*	BSL-3	Inventory discrepancy - individual failed to note vial had been destroyed.	Not a select agent
9/2/2004	Release	Washington University at St. Louis	Academic	*Yersinia pestis*	BSL-3	Unlikely exposure to biohazardous waste that contained sealed culture plates containing select agent.	Closed
3/31/2006	Release	William Beaumont Hospital	Commercial	*Coccidioides immitis*	BSL-2	Potential exposure - laboratorian working with diagnostic sample on benchtop.	Closed
4/11/2006	Release	William Beaumont Hospital	Commercial	*Brucella melitensis*	BSL-2	Potential exposure - laboratorian working with diagnostic sample on benchtop.	Closed
9/12/2006	Release	William Beaumont Hospital	Commercial	*Brucella melitensis*	BSL-2	Potential exposure - laboratorian working with diagnostic sample on benchtop.	Closed
3/29/2005	Loss	WRAIR/NMRC	Government - Federal	*Francisella tularensis*	BSL-3	Discrepancy in shipment - 3 vials not shipped.	Closed
3/28/2004	Loss	Yale University	Academic	*Coxiella burnetii (Nine mile strain)*	BSL-2	Inventory discrepancy due to poor record-keeping.	Not a select agent

Exhibit No. 16

Animal Health and Welfare: FMD Data Archive

Introduction

During the course of the Foot and Mouth Outbreak 2001 MAFF and then its successor Department Defra created large volumes of data on every conceivable element of the outbreak. Mindful of the fact from very early on in April 2001 that the outbreak was going to be of enormous consequence to the UK, the staff of the Joint Co-ordination Centre in London took the decision to make sure that all possible data sources were captured and protected as the outbreak progressed. The quality of the data from the early stages of the outbreak was less than perfect and although much time and effort has been expended in checking and verifying data and going back to original sources we would not claim by any means that the data set had been brought to a perfect state. But, that fact does not deny its value as the most completely documented major outbreak of animal disease to date.

For the first time ever for a major epidemic we have most of the salient data available in electronic form. This dataset is available to any bona-fide researcher world-wide who is prepared to observe modest confidentiality conditions.

Some elements of the data have no data protection implications and these are presented for public consumption. The elements show in graphical form how the epidemic progressed and regressed and how the numbers of animals destroyed accumulated on a county by county basis.

In the deeper archive, for the academic researcher, all the data elements that we collected are accessible and we provide a managed service to make access to large data sets by means of FTP or CD ROM possible.

In making this data available we meet the stated wish of both the Royal Society Report and the Lessons Learned Inquiry. Both asked that the data be made available so that scientists and others charged with managing animal disease could use the information to advantage in understanding major epidemics and all the elements that form part of disease control.

The Report from the Royal Society shows clearly the major impact that the FMD 2001 epidemic had on the UK:

"That outbreak was the worst experienced by Britain since proper records began and involved 2030 cases spread across the country. Some 6 million animals were culled (4.9 million sheep, 0.7 million cattle and 0.4 million pigs), which resulted in losses of some £3.1 billion to agriculture and the food chain. Some £2.5 billion was paid by the Government in compensation for slaughtered animals and payments for disposal and clean up costs. About 4 million of the animals were culled as part of disease control (1.3 million on infected premises, 1.5 million on farms defined as dangerous contacts not contiguous with the infected premises, and 1.2 million on contiguous premises, many of which were also defined as dangerous contacts). The others died under various types of 'welfare cull'. At one stage, it was suggested that in addition to the six million animals mentioned above there could have been up to 4 million further young animals killed 'at foot' (i.e. slaughtered but not counted). Defra believe that these estimates of additional 'at foot' animals are, however, likely to be high, because at least some of these young animals were included in their original figures. The foot-and-mouth outbreak had serious consequences upon tourism-in both city and country-and other rural industries." (The Royal Society - Infectious Diseases in Livestock, 2002.)

Exhibit No. 17

BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, AND SCIENCE
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Billions for Biodefense: Federal Agency Biodefense Funding, FY2006–FY2007

CLARENCE LAM, CRYSTAL FRANCO, and ARI SCHULER

Since 2001, the United States government has spent substantial resources on preparing the nation against a bioterrorist attack. Earlier articles in this series analyzed the civilian biodefense funding by the federal government from fiscal years 2001 through 2006. This article updates those figures with budgeted amounts for fiscal year 2007, specifically analyzing the budgets and allocations for biodefense at the Department of Health and Human Services, the Department of Homeland Security, the Department of Agriculture, the Environmental Protection Agency, the Department of State, and the National Science Foundation.

FEDERAL FUNDING for civilian biodefense increased by $112 million in the President's FY2007 budget, for a total request of $5.24 billion (Table 1). Excluding BioShield funds made available in FY2004 and FY2005, the FY2007 budget request continues a trend of incremental increases in civilian biodefense funding since FY2001 (Figure 1). The President's FY2007 budget request includes funding increases for most of the agencies involved in biodefense, with the largest increase being allocated to the Department of Health and Human Services (HHS) for programs such as the Strategic National Stockpile (SNS), biodefense research, and countermeasure development. HHS is the chief recipient of the proposed federal biodefense monies, with 82% of the FY2007 proposed funds going to this agency (Figure 2) and 73% of biodefense-related funds since FY2001 (Figure 3). Funding increases also have been requested for the Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Department of State. The most significant decrease in biodefense funding is proposed for the Department of Homeland Security (DHS), and a smaller budget cut is proposed for the National Science Foundation (NSF).

METHODS AND SOURCES

Tracking expenditures in civilian biodefense poses a number of challenges; some of these are inherent in tracking government expenditures in general, while other issues are specific to civilian biodefense. It was first necessary to determine what was actually spent as opposed to what was budgeted or appropriated. Typically, in a budget cycle, actual numbers are available for the prior year, with funding estimates available for the current year, and the President's budget request available for the upcoming year. In this article, unless otherwise noted, FY2001–FY2005 amounts are based on actual numbers, FY2006 amounts are estimated, and FY2007 numbers represent the President's budget request.

Finding accurate and up-to-date sources of information is another challenge. Departmental "Budget in Brief" documents were analyzed when available, but these reports often do not separate out civilian biodefense efforts, or they may include only partial information. Entire agency or departmental budgets also were examined, yet this was not always an effective method, as civilian biodefense expenditures could be contained within

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TABLE 1. U.S. GOVERNMENT CIVILIAN BIODEFENSE FUNDING, FY2001–FY2007 (IN $MILLIONS)

	FY2001 (actual)	*FY2002 (actual)*	*FY2003 (actual)*	*FY2004 (actual)*	*FY2005 (actual)*	*FY2006 (estimate)*	*FY2007 (budget)*	*Total*
Department of Health and Human Services	271.0	2,940.0	3,986.0	3,700.0	4,153.0	4,085.0	4,253.0	23,388.0
Department of Homeland Security[a,b,c]	—	—	418.6	1,704.3	2,946.2	554.3	374.2	5,997.6
Department of Agriculture[d]	—	—	200.0	109.0	298.0	253.0	322.0	1,182.0
Environmental Protection Agency	20.0	187.2	132.9	118.7	97.4	129.1	184.0	869.4
Department of State	3.8	70.9	67.2	67.1	67.2	71.1	77.7	425.0
National Science Foundation	0.0	9.0	31.3	31.0	31.0	31.3	25.0	158.5
Total USG Civilian Biodefense Funding	**294.8**	**3,207.1**	**4,836.0**	**5,730.1**	**7,592.8**	**5,123.8**	**5,235.9**	**32,020.4**
Department of Defense[e]	135.0	526.0	161.7	274.8	263.7	—	—	1,361.2
Spent through FY2006	26,784.5							
Spent through FY2006 + FY2007 Budget	32,020.4							

[a] The Department of Homeland Security (DHS) was created in FY2003.

[b] DHS was unable to provide complete data. Accordingly, some items are missing. See Table 3.

[c] DHS FY2004 and FY2005 budgets include one-time advanced appropriations for Project BioShield of $890 million and $2.5 billion, respectively, obligated for use through FY2013.

[d] FY2001–FY2002 numbers not available due to budget methods used by USDA.

[e] Exact numbers unavailable due to inability of press office to provide information and lack of clear and complete published information. DoD is no longer counted in the total due to incomplete information.

Sources: USDA Budget; USDA Press Office; USDA Budget Office; Office of Plans and Systems, Office of the Secretary Media Public Affairs, Department of Defense; Congressional Budget Office; AAAS Report on FY2007 Research and Development in DoD; DoD RDT&E Defense-Wide Budget; EPA Budgets in Brief and Congressional Justifications, FY2002–FY2007; HHS Budget Office; HHS Press Office; HHS Budgets in Brief FY2006–FY2007; DHS Budget; DHS Press Office; DHS FY2006 Congressional Justification (page 6); OMB Budget Appendix; DHS Program Officials; DHS FY2006 Appropriations Bill (H.R. 2360), Public Law 109-62; U.S. Department of State Public Communication Division; U.S. Department of State Budget in Brief FY2007; NSF Office of Legislative & Public Affairs, NSF Program Directors.

broader line items. Ultimately, when further information was deemed necessary, data were acquired by contacting the public affairs and budget offices of every agency listed in the report. This methodology was based on the principle that the numbers from the respective budget offices would be the most accurate and current, as these were the same numbers then assigned to the program offices responsible for executing programs within the agency.

It should be noted that budget line items are not necessarily indicative of size or location of programs. Many programs may be consolidated under one line item (such as DHS's Science & Technology), or a program may have many components (such as BioShield, which is administered by HHS with guidance from DHS). In other cases, work may be done by one department and reimbursed by another: For example, work done by the Agency for Healthcare Research and Quality (AHRQ) has been reimbursed by the Health Resources and Services Administration (HRSA) and the Office of State and Local Preparedness Office of the Assistant Secretary for Public Health Emergency Preparedness of HHS.

A challenge for this and the previous years' articles[1,2] was to distinguish which items should be considered civilian biodefense and which should not. Here, civilian biodefense funding includes programs, research, and administrative costs that prevent or mitigate bioterrorism's effects on civilians. Federal budgets for programs intended for the general prevention and mitigation of weapons of mass destruction (WMD), such as "chemical, biological, radiological, and nuclear countermeasures" (e.g., some EPA detection items and BioShield), do not

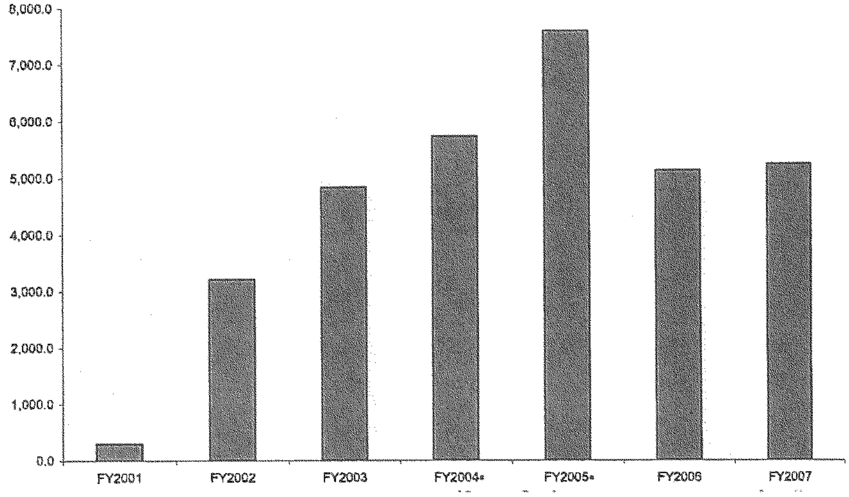

FIGURE 1. CIVILIAN BIODEFENSE FUNDING BY FISCAL YEAR, FY2001–FY2007 (IN MILLIONS)

distinguish how much of the program is specifically targeted at civilian biodefense, so they were included in their entirety as a practical measure. Multiple application programs (e.g., HHS's Medical Reserve Corps or DHS's National Disaster Medical System) that provide a substantial benefit in responding to an incident of civilian bioterrorism were included in their entirety. Physical security upgrades and other infrastructure protection also were included, but it should be noted that these upgrades cover both laboratory and general security (such as office buildings). This overall methodology led to some overestimation of biodefense funding, because it is likely that some of those funds will be spent on non-biodefense programs.

Programs that are not specifically directed at bioterror agents (e.g., the National Institute of Health's nuclear/radiological medical countermeasures or pandemic flu programs) were not included. Also not included were programs that include a small, undefined biological component (such as many of the DHS Preparedness Directorate's "All Hazards" grants and training), as well as routine surveillance that does not focus specifically on civilian biodefense but may play a role in such detection (such as the Department of Agriculture's Food Safety and Inspection Service, which focuses on chemical contamination and natural microbial contamination).

The Department of Defense (DoD) has a large base of research in chemical and biological countermeasures for warfighter protection. However, because of the focus on the warfighter and not the civilian, these numbers were excluded from this article. Some products, such as protective gear and detectors, do not have civilian mass market applications, so these DoD programs are not defined as civilian biodefense in this article. Some DoD research has direct civilian benefit, but because the majority of these funds are primarily military in application, these lines were excluded from calculation of total DoD expenditures.

Finally, there are two items of importance that should be noted in this year's update to earlier "Billions for Biodefense" articles.[1,2] The first is the absence of DoD data for both FY2006 and FY2007 and the exclusion of DoD numbers from the overall civilian biodefense funding totals (Table 1). The DoD figures were separated from the calculated totals in this edition of "Billions for Biodefense" for the following reasons:

- Officials in the DoD's Office of the Secretary had difficulty distinguishing between military and civilian biodefense programs within their own budget.
- The authors were unable to distinguish civilian biodefense programs from military biodefense using DoD Budget Justification materials.[3]
- Some programs identified for previous "Billions for

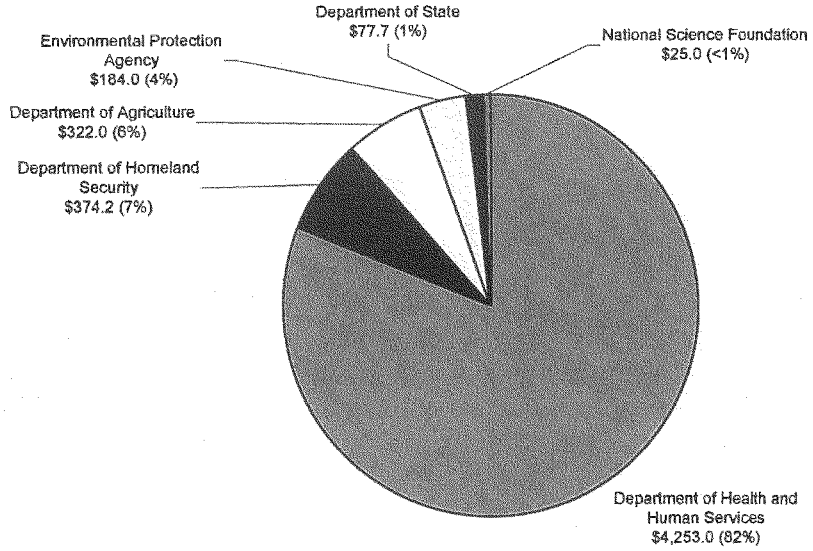

FIGURE 2. PROPOSED CIVILIAN BIODEFENSE FUNDING BY AGENCY, FY2007 (IN MILLIONS)

Biodefense" articles[1,2] could not be found in the FY2006 or FY2007 budget documents and could not be provided by DoD.

- It was unclear what percentage of funding was being directed to biodefense versus chemical defense.

The second major change was the documenting of additional DHS biodefense efforts that were not included in last year's article. We have revised the totals from last year's article, and DHS efforts from FY2001–FY2007 (including the President's budget request) total $6 billion from the data that is available.

CIVILIAN BIODEFENSE FUNDING BY FEDERAL AGENCY

Department of Health and Human Services

For FY2007, the President's budget for HHS requests an increase of $168 million, or about 3.95%, for a total of $4.253 billion. Most of the money requested for HHS is provided to programs and agencies within the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) (Figure 4). Most of the HHS line item values, with a few exceptions, are comparable to their FY2006 amounts (Table 2).

The President has requested that NIH create a $160 million fund within the Office of the Director for a program devoted to the advanced development of biodefense countermeasures identified as likely targets for potential acquisition by Project BioShield. Funding for this program for FY2007 will be allocated as a subset of the Biodefense Research money request. Although $50 million was included within the National Institute of Allergy and Infectious Disease (NIAID) biodefense research base to fund similar activities in FY2006, it was not designated as a separate fund. This FY2007 advanced countermeasure development fund represents an increase of $110 million for such activities and is the largest increase in HHS biodefense-related funds for FY2007.[4]

The Strategic National Stockpile is slated to receive a budget increase of $68 million, for a total of $593 million. Of this, $79 million will be used to continue funding a "Federal Mass Casualty Initiative" for the purchase of portable hospital treatment units that are expected to be used to expand hospital surge capacity in a mass casualty emergency such as a bioterrorist attack. This represents an increase of $29 million in FY2007 over the $50 million that was appropriated in FY2006.

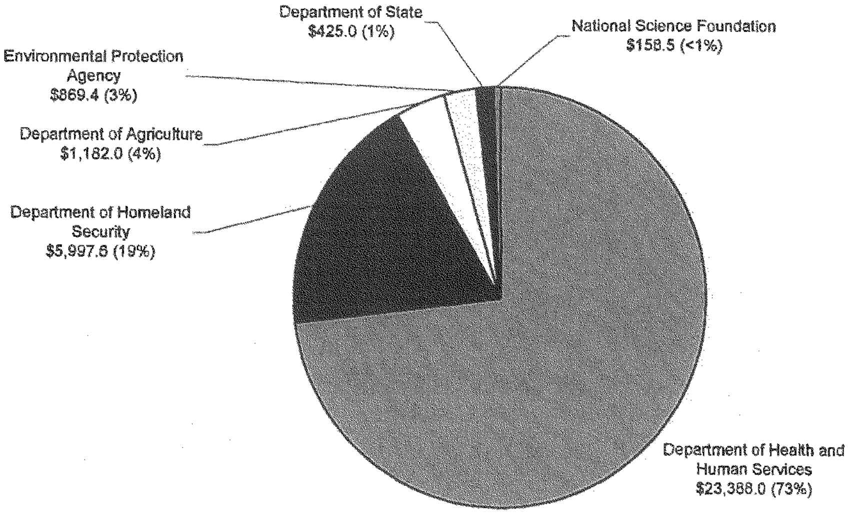

FIGURE 3. CUMULATIVE CIVILIAN BIODEFENSE FUNDING BY AGENCY, FY2001–FY2007 (IN MILLIONS)

Finally, CDC has a proposed cut of $31 million, or about 23%, for its Biosurveillance Initiative, which is intended to strengthen surveillance, containment, and outbreak response measures. According to HHS budget documents, this reduction will be partially offset by FY2007 pandemic influenza emergency funds designated to support the Biosurveillance Initiative.[4]

Department of Homeland Security

For FY2007, the President's budget for DHS proposes a decrease of $180 million, or about 31%, for a total of $374.2 million (Table 3). This sum represents an estimate of the total amount of biodefense funds requested for DHS, since precise figures for its BioSurveillance program could not be obtained.

The FY2007 budget decrease is primarily due to a one-time emergency supplemental in FY2006 providing additional funds to the National Disaster Medical System (NDMS) for deployment during the response to Hurricane Katrina. NDMS was originally appropriated $34 million for FY2006[6] but received $100 million in additional appropriations through an emergency supplemental,[7] signed on September 8, 2005, to provide disaster relief funds for use as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

The Office of the Chief Medical Officer was created in July 2005 to serve as the department's chief liaison to other federal agencies in coordinating overall efforts to prevent and respond to a biological terrorist attack.[8] Located within the newly restructured Preparedness Directorate, it is proposed to have a budget of $3 million.

The Metropolitan Medical Response System (MMRS), a program also within the Preparedness Directorate, is intended to augment and improve emergency preparedness systems in order to increase the effectiveness of first responders to a public health emergency.[9] It is not funded in the proposed FY2007 budget, resulting in a reduction of $30 million. The President's past FY2005 and FY2006 budget proposals also failed to request funding for MMRS after the program rated poorly in the Office of Management and Budget's annual program assessments.[10,11] Congressional appropriators disapproved[12,13] of the program's elimination by declaring it a "vital system"[12] and subsequently reinstated $30 million to MMRS for each fiscal year.[14]

The Science and Technology Directorate budget has a proposed reduction of $39 million, or about 10%, as a result of a decrease in funds for biological countermeasures. The Directorate's FY2007 request of $337 million includes $23 million for planning, designing, and developing a National Bio and Agrodefense Facility to

TABLE 2. DEPARTMENT OF HEALTH AND HUMAN SERVICES CIVILIAN BIODEFENSE FUNDING, FY2001–FY2007 (IN $MILLIONS)

	FY2001 (actual)	*FY2002 (actual)*	*FY2003 (actual)*	*FY2004 (actual)*	*FY2005 (actual)*	*FY2006 (estimate)*	*FY2007 (budget)*
CDC							
CDC: Upgrading State and Local Capacity	67	940	939	918	927	824	824
BioSurveillance Initiative	0	0	0	22	79	133	102
Supplemental Appropriations (Smallpox)	0	0	100	0	0	0	0
Upgrading CDC Capacity	22	141	157	0	0	0	0
Anthrax Vaccine Research	18	18	18	0	0	0	0
Upgrading CDC Capacity/Anthrax Vaccine Research[a]	0	0	0	169	158	150	136
Botulinum Antitoxin Research	—	—	—	—	—	—	3
Independent Studies	11	2	2	0	0	0	0
Other	10	46	20	0	0	0	0
Strategic National Stockpile (SNS)[b]	81	1,157	398	0	467	475	514
Federal Mass Casualty Initiative (additional to the SNS)	0	0	0	0	0	50	79
Subtotal, CDC	**209**	**2,304**	**1,634**	**1,109**	**1,631**	**1,632**	**1,658**
HRSA							
Hospital Preparedness and Infrastructure	0	135	515	515	487	449	449
Emergency Response Demonstration[c]	0	0	0	0	0	25	25
Education Incentives for Medical Curriculum	0	0	28	28	28	21	12
Smallpox Compensation	0	0	42	0	0	0	0
Subtotal, HRSA	**0**	**135**	**585**	**543**	**515**	**495**	**486**
Office of the Secretary							
Office of Public Health and Emergency Preparedness	0	50	47	41	41	41	43
Medical Reserve Corps	0	3	10	10	10	10	22
Healthcare Provider Credentialing	0	0	0	0	0	0	7
Subtotal, Office of the Secretary	**0**	**53**	**57**	**51**	**51**	**51**	**72**
Subtotal, PHSSEF Biosecurity[d]	**209**	**2,492**	**2,276**	**1,703**	**2,197**	**2,178**	**2,216**

Table 2. Department of Health and Human Services Civilian Biodefense Funding, FY2001–FY2007 (in $millions) (continued)

	FY2001 (actual)	*FY2002 (actual)*	*FY2003 (actual)*	*FY2004 (actual)*	*FY2005 (actual)*	*FY2006 (estimate)*	*FY2007 (budget)*
FDA							
Food Safety	1	98	97	116	150	158	178
Vaccines/Drugs/Diagnostics (relabeled "Medical Product Countermeasures")	6	46	53	53	57	57	57
Physical Security	2	13	7	7	7	7	7
Subtotal FDA	**9**	**157**	**157**	**176**	**214**	**222**	**242**
NIH							
Biodefense Research (NIAID)	53	199	687	1,629	1,548	1,655	1,610
Advanced Development of Biodefense Countermeasures[e]	—	—	—	—	—	—	160
rPA Anthrax Vaccine Intermediate Scaleup	0	0	123	117	0	0	0
MVA Smallpox Vaccine Intermediate Scaleup	0	0	0	75	45	0	0
Extramural BT Research Facilities[f]	0	92	743	0	149	30	25
Subtotal NIH	**53**	**291**	**1,553**	**1,821**	**1,742**	**1,685**	**1,795**
Total HHS Civilian Biodefense Funding	**271**	**2,940**	**3,986**	**3,700**	**4,153**	**4,085**	**4,253**

[a] These line items were counted separately until the President's FY2006 budget.

[b] The SNS was located in the HHS Office of the Secretary for FY2001–FY2003 and 2005–2007. In FY2004, it was located in the Department of Homeland Security. It is now a CDC function.

[c] This line item is additional to the Hospital Preparedness and Infrastructure item.

[d] Some HHS biodefense funds are specifically requested through the Public Health Social Services Emergency Fund (PHSSEF). Placing funds in the PHSSEF enables them to be appropriated in one place and then allocated to targeted biodefense activities.

[e] This fund is to be overseen by the Office of the NIH Director. The money for this fund is allocated from the existing Biodefense Research program.

[f] FY2007 Extramural BT Research Facilities funds are to be used to construct new university BSL-3 labs and to renovate existing university labs to BSL-3 standards. This line item is the only funding stream being allocated directly toward construction and upkeep of BT-specific facilities. It is assumed that funding for upkeep of intramural NIH facilities used in BT-related research is encompassed in the NIH intramural research funding. The NIH Buildings and Facilities line item, although budgeted close to $1 billion each year, is focused on physical maintenance of all NIH facilities. The authors do not consider the NIH Buildings and Facilities account to be directly relevant to biodefense and have not included it in these calculations.

Sources: HHS Budget Office; HHS Press Office; HHS Budgets in Brief FY2006–FY2007 http://www.hhs.gov/budget/07budget/2007BudgetInBrief.pdf, pg. 36

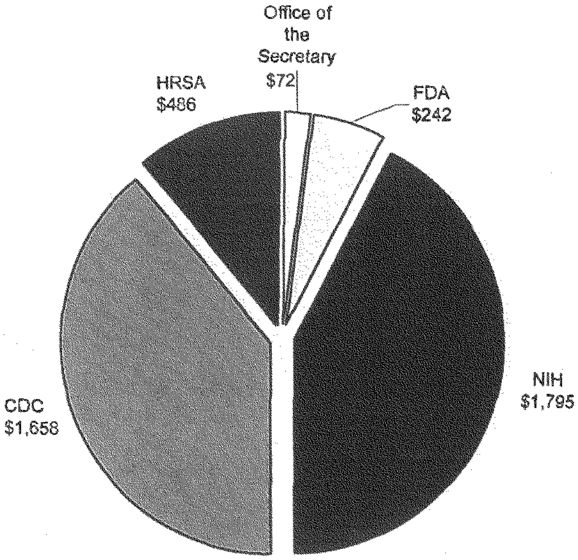

FIGURE 4. HHS PROPOSED CIVILIAN BIODEFENSE FUNDING, FY2007 (IN MILLIONS)

research biological threats caused by human and animal diseases.[15]

In FY2004, an advanced appropriation of $5.6 billion was awarded to BioShield for use through FY2013, of which $890 million was made available in FY2004 and $2.5 billion was made available in FY2005. The remaining balance of $2.2 billion is to be made available beginning in FY2009.[16] As of FY2006, $2.3 billion of the $3.5 billion in total BioShield funds available prior to FY2009 remained unobligated.[17]

Additionally, a number of line items that could not be tracked in previous "Billions for Biodefense" articles[1,2] were updated for this version when data became available. Particular line items also were shifted when compared to previous articles to reflect the restructuring of DHS directorates after the department's second-stage review in October 2005.

Department of Agriculture

For FY2007, it is proposed that USDA receive a funding increase of about $69 million, or about 27%, for a total of $322 million. This represents an increase in program funding for the Food and Agriculture Defense Initiative of $127 million, or about 65%, when accounting for the completion of the BSL-3 facility in Ames, Iowa (Table 4).

Most of the increases stem from an expansion of the department's food and agricultural monitoring and research activities. Within food defense, the Food Emergency Response Network (FERN) is a collaborative effort between the USDA's Food Safety and Inspection Service (FSIS) and HHS to operate a network of laboratories intended to detect and distinguish biological, chemical, and radiological agents in food.[18] FERN was provided a budget increase of $16 million, and the Agricultural Research Service (ARS) was provided an additional $14 million for Food Defense Research compared to FY2006. Overall, an increase of $30 million is proposed for the Food Defense component of the Food and Agriculture Defense Initiative.

The Animal and Plant Health Inspection Service is budgeted an increase of $43 million, or about 49%, to a total of $130 million for enhanced surveillance, and the ARS proposes an increase of $24 million for agricultural defense research. Funding for the completed Ames, Iowa, BSL-3 facility was eliminated, for a decrease of $58 million in FY2007. Overall, an increase of $39 mil-

TABLE 3. DEPARTMENT OF HOMELAND SECURITY CIVILIAN BIODEFENSE FUNDING, FY2003–FY2007 (IN $MILLIONS)

	FY2003 (actual)	*FY2004 (actual)*	*FY2005 (actual)*	*FY2006 (estimate)*	*FY2007 (budget)*
Preparedness Directorate[a]					
National Disaster Medical System	5	82	34	134	34
Strategic National Stockpile	0	398	0	—[b]	—[b]
Metropolitan Medical Response System (MMRS)	50	50	30	30	0
BioShield	0	885	2,507	0[c]	0[c]
Office of the Chief Medical Officer[d]	—	—	—	—	3
BioSurveillance[e]	0	0	12.5	14.1	—[f]
Science & Technology Directorate					
Biological Countermeasures (includes HSARPA, BioSurveillance/ BioWatch, National Bio and Agrodefense Facility, and other research efforts)	362	285	362.7	376.2	337.2
National Biodefense Analysis and Countermeasures Center[g]	1.6	4.3	35[h]	0	0
Total DHS Civilian Biodefense Funding	**418.6**	**1,704.3**	**2,946.2**	**554.3**	**374.2**

[a] Formerly known as the Emergency Preparedness and Response Directorate.

[b] The Strategic National Stockpile was transferred to HHS (CDC).

[c] Funds appropriated for BioShield in prior years will be used in the current year.

[d] Office of the Chief Medical Officer was created in 2005.

[e] Formerly located within the Information Analysis and Infrastructure Protection Directorate.

[f] DHS was unable to provide this amount.

[g] DHS determined the construction cost of the NBACC facility to be $128 million. This full amount was appropriated by Congress in FY2003–FY2005 ($5m, $88m, $35m each fiscal year, respectively). According to a Congressional Research Service report, some "funds appear to be have been reprogrammed into other program elements."[5] No additional funds have been requested for NBACC construction since FY2005, so "it is unclear what funds will be used to construct the NBACC facility in future years."[5]

[h] This is the FY2005 amount appropriated by Congress. The actual amount is unavailable.

Sources: DHS FY2007 Budget in Brief http://www.dhs.gov/dhspublic/interweb/assetlibrary/Budget_BIB_FY2007.pdf; DHS Press Office; OMB Budget Appendix; DHS Program Officials; DHS FY2006 Appropriations Bill (H.R. 2360), Public Law 109-62; DHS FY2006 Congressional Justification http://www.dhs.gov/interweb/assetlibrary/Budget_PBO_FY2006.pdf pg.6; DHS FY2006 Congressional Justification, Science and Technology Directorate http://www.ucop.edu/research/homelandsecurity/documents/STFY2006CJ2022005Final1.pdf.

lion is proposed for the Agricultural Defense component of the Food and Agriculture Defense Initiative.

Environmental Protection Agency

The President's budget for the Environmental Protection Agency (EPA) is requesting an increase of $54.9 million, or about 43%, to a total of $184.04 million. The FY2007 budget allocates an additional $33.4 million to the Water Sentinel program, for a total of $54 million, and an increase of $21 million to EPA's Homeland Security research and preparedness response program, for a total of $97.6 million (Table 5). According to EPA budget documents, the Public Health Security and Bioterrorism Response and Preparedness Act of 2002 and Homeland Security Presidential Directives (HSPD 7 and 9) direct EPA to help the water sector develop and implement both protective measures against terrorism and comprehensive surveillance programs.[19] The increase in FY2007 biodefense funds will help support these programs.

State Department

For FY2007, the President is requesting an increase of $6.61 million, or about 9.3%, to a total of $77.68 million for the State Department's biodefense programs. The Worldwide Security Upgrades Chemical and Biological Program, responsible for increases of diplomatic personnel and facilities in the face of terrorism, is budgeted at $20.5 million for FY2007 (Table 6).[20] In addition,

Table 4. Department of Agriculture Civilian Biodefense Funding, FY2001–FY2007 (in $millions)

	FY2001[a]	*FY2002*[a]	*FY2003 (actual)*	*FY2004 (actual)*	*FY2005 (actual)*	*FY2006 (estimate)*	*FY2007 (budget)*
Food and Agricultural Defense Initiative							
Food Defense							
FSIS	—	—	1	1	3	3	3
Food Emergency Response Network (FERN)	—	—	0	0	3	3	19
Enhanced Inspections	—	—	0	2	2	2	2
Lab Upgrades/Physical Security	—	—	1	3	3	6	6
Education/Training	—	—	2	2	3	4	4
Other Activities	—	—	4	4	4	5	5
ARS Food Defense Research	—	—	2	2	8	9	23
Subtotal, Food Defense	—	—	**10**	**14**	**26**	**32**	**62**
Agricultural Defense							
ARS							
Ames, IA, BSL-3 Facility	—	—	143	0	121	58	0
Research	—	—	10	17	21	25	49
National Plant Disease Recovery System	—	—	0	0	2	2	6
Foreign Disease Weed Science Laboratory, Frederick, MD	—	—	0	0	0	0	0
Cooperative State Research, Education, and Extension Service (CSREES)							
Regional Diagnostic Network	—	—	0	8	9	10	12
Higher Education Agrosecurity Program	—	—	0	0	0	0	5
APHIS Pest Detection/Animal Health Monitoring							
Enhanced Surveillance	—	—	0	38	80	87	130
BioSurveillance	—	—	0	0	2	2	3
Plant Safeguarding Activities	—	—	—	17	17	17	23
Select Agents—Plants and Animals	—	—	0	0	3	3	5
National Veterinary Stockpile	—	—	0	1	3	3	8
Other Activities	—	—	37	14	14	14	19
Subtotal, Agricultural Defense	—	—	**190**	**95**	**272**	**221**	**260**
Total USDA Civilian Biodefense Funding	—	—	**200**	**109**	**298**	**253**	**322**

[a] USDA Press and Budget offices were unable to provide numbers for these years.

Sources: USDA FY2007 Budget Summary http://www.usda.gov/agency/obpa/Budget-Summary/2007/FY07budsum.pdf; USDA Press Office; USDA Budget Office; USDA Program Officials.

Table 5. Environmental Protection Agency Civilian Biodefense Funding, FY2001–FY2007 (in $Millions)

	FY2001 (actual)	*FY2002 (actual)*	*FY2003 (actual)*	*FY2004 (actual)*	*FY2005 (actual)*	*FY2006 (estimate)*	*FY2007 (budget)*
Capitol Hill Anthrax Cleanup	20	—	—	—	—	—	—
Clean and Safe Water: Homeland Security[a]	0	3.8	—	—	—	—	—
Safe Food: Homeland Security[b]	0	0	—	—	—	—	—
Waste Management: Homeland Security[b]	0	3.2	—	—	—	—	—
Quality Environmental Information: Homeland Security[b]	0	0.6	—	—	—	—	—
Sound Science/Improved Understanding/Innovation: Homeland Security[b]	0	0.6	—	—	—	—	—
Deterrent to Pollution: Homeland Security[b]	0	3.5	—	—	—	—	—
Effective Management: Homeland Security[b]	0	0	—	—	—	—	—
Emergency Supplemental Funds[c]	0	175.6	0	0	0	—	—
Water Safety Grants to States	0	0	4.5	5	5	5	5
Clean and Safe Water: Homeland Security, Critical Infrastructure Protection, Protect Human Health	0	0	14.2	27.4	—	—	—
Clean Land: Homeland Security Preparedness, Response and Security	0	0	37.6	27.3	—	—	—
Healthy Communities & EcoSystems: Homeland Security Prep/Resp/Sec, Chem/Org/Pesticide Risks	0	0	0.7	2.3	—	—	—
Healthy Communities & EcoSystems: Homeland Security Prep/Resp/Sec, Science and Research	0	0	31	29	—	—	—
Compliance and Environmental Stewardship: Homeland Security: Critical Infrastructure Protection, Improve Compliance	0	0	4.2	3.9	—	—	—
Enabling and Support Programs: Homeland Security, Office of Waste and Emergency Response	0	0	0	0.6	—	—	—
Enabling and Support Programs: Homeland Security, Office of Administration and Resources Management, Protection of EPA Personnel and Infrastructure	0	0	40	19.3	—	—	—
Enabling and Support Programs: Homeland Security, Office of Environmental Information, Communication and Information	0	0	0	3.8	—	—	—
Enabling and Support Programs: Homeland Security, Office of International Activities, Protection of EPA Personnel and Infrastructure	0	0	0	0	—	—	—
Enabling and Support Programs: Homeland Security, Office of the Administrator, Communication and Information	0	0	0.9	0	—	—	—
Homeland Security: Communication and Information	—	—	—	—	4.3	6.8	7.1
Homeland Security: Critical Infrastructure Protection	—	—	—	—	11.2	20.6	54.1
Homeland Security: Preparedness, Response and Recovery	—	—	—	—	56.4	76.6	97.6
Homeland Security: Protection of EPA Personnel and Infrastructure	—	—	—	—	20.5	20.2	20.3
Total EPA Civilian Biodefense Funding	**20**	**187.2**	**132.9**	**118.7**	**97.4**	**129.1**	**184.0**

[a] Numbers for additional years are included in other line items, such as Clean Land.

[b] Due to EPA reorganization, these activities fell under new headings beginning in FY2003.

[c] This bill includes a number of relevant line items, but a precise breakdown that accounts for all $175 million could not be found.

Sources: Compiled from EPA Budgets in Brief and Congressional Justifications, FY2002–FY2007 http://www.epa.gov/ocfo/budget/2007/2007bib.pdf.

TABLE 6. DEPARTMENT OF STATE CIVILIAN BIODEFENSE FUNDING, FY2001–FY2007 (IN $MILLIONS)

	FY2001 (actual)	*FY2002 (actual)*	*FY2003 (actual)*	*FY2004 (actual)*	*FY2005 (actual)*	*FY2006 (estimate)*	*FY2007 (budget)*
World Security Upgrades: Chem/Bio Program	3.8	3.9	15.2	17.1	17.1	19	20.5
Worldwide Security Upgrades: Chem/Bio Preparedness[a]	—	—	—	—	—	—	0.98
BioRedirection[b]	0	67	52	50	—	—	—
Nonproliferation of WMD Expertise	—	—	—	—	50.1	52.1	56.2
Total State Department Civilian Biodefense Funding	**3.8**	**70.9**	**67.2**	**67.1**	**67.2**	**71.1**	**77.7**

[a] This line item was added for FY2007, and funds are to be used to buy masks and other protective equipment.
[b] The BioRedirection program was folded under the Nonproliferation of WMD Expertise item in 2005.
Sources: U.S. Department of State Public Communication Division; U.S. Department of State Budget in Brief FY2007 http://www.state.gov/m/rm/c6112.htm.

the State Department is requesting $980,000 for Chemical/Biological Preparedness under the Worldwide Security Upgrades program. These funds are intended to provide training for use and maintenance of escape masks for protection of personnel in the event of a chemical or biological attack at overseas missions.[20]

The Nonproliferation of WMD Expertise (NWMDE) line item is provided $56.2 million for four programs: Science Centers, Bio-Chem Redirection, the BioIndustry Initiative, and Iraqi WMD Scientist Redirection. All of these focus on redirecting and engaging scientists from former bioweapons programs to "sustainable civilian scientific research."[21]

National Science Foundation

For FY2007, the President's budget for the National Science Foundation proposes a decrease of $4 million, or 20%, for a total of $25 million to fund its Ecology of Infectious Diseases and Microbial Genome Sequencing programs.

Funding for Sensor and Sensor Networks, established as a short-term program to bolster particular sensor re-

TABLE 7. NATIONAL SCIENCE FOUNDATION CIVILIAN BIODEFENSE FUNDING, FY2001–FY2007 (IN $MILLIONS)

	FY2001 (actual)	*FY2002 (actual)*	*FY2003 (actual)*	*FY2004 (actual)*	*FY2005 (actual)*	*FY2006 (estimate)*	*FY2007 (budget)*
Ecology of Infectious Diseases, BIO Directorate	0	4.1	6	6	6	6	6
Ecology of Infectious Diseases, GEO Directorate	0	0	4	4	4	4	4
Microbial Genome Sequencing, Bio Directorate	0	4.8	15	15	15	15	15
Microbial Genome Sequencing, CISE Directorate	0	0	2	2	2	2	0
Sensors and Sensor Networks, Engineering Directorate	0	0	4.3	4	4	4.3	0
Total NSF Civilian Biodefense Funding	**0**	**8.9**	**31.3**	**31**	**31**	**31.3**	**25**

Sources: NSF Office of Legislative & Public Affairs, NSF Program Directors.

search, is to be eliminated in FY2007. Total funding for Microbial Genome Sequencing will decrease to $15 million after a reduction of $2 million formerly funded by the Computer, Information Science, and Engineering (CISE) Directorate (Table 7).

Department of Defense

For the president's FY2007 budget request, the authors were able to find numbers for the line items of Civil Support Teams, Cooperative Threat Reduction: Biological Weapons Proliferation Prevention, and Chemical and Biological Defense. The Civil Support Teams, which are jointly funded by DoD and state national guard units and provide detection capabilities for local authorities during WMD events, are not funded in the FY2007 budget according to DoD documents.[22]

The Cooperative Threat Reduction (CTR) Program was established with the intention of preventing the proliferation of WMD and related materials, technologies, and expertise from states of the former Soviet Union. Biological Weapons (BW) Proliferation Prevention, a program within CTR, is divided into three initiatives: elimination of former Soviet bioweapons production infrastructure; biosecurity and biosafety upgrades and increased biological threat agent detection and response; and cooperative biological research with former Soviet bioweapons scientists. The CTR BW Proliferation Prevention Program's proposed budget request is $68.4 million in FY2007 (Table 8).[3] The authors also updated program funding levels for previous years, which were unavailable for past "Billions for Biodefense" articles.[1,2]

The Chemical and Biological Defense program was not included in the DoD biodefense budget calculation because it includes many items that are not applicable to civilian biodefense. DoD could not provide numbers for other biodefense-related programs, and thus these numbers have not been included.

The budget numbers for DoD were not counted in this article's overall total for civilian biodefense funds due to the absence of complete and clear data from the agency. Some of the data related to DoD biodefense funding was inaccessible, and the authors often were unable to discern which funds were allocated specifically for civilian biodefense efforts. DoD allocates a large sum of money toward Chemical and Biological Defense, but it is unclear what percentage of that goes toward biological versus chemical defense, what percentage is spent on laboratory research that will lead to civilian countermeasures, and what percentage is military equipment development (sensors, vehicles, etc.) that will not be deployed for civilian use. As such, the authors have chosen to make the DoD data available but have excluded it from the overall total.

CONCLUSION

The President's proposed FY2007 budget requests an increase of $112 million over the FY2006 civilian biode-

TABLE 8. DEPARTMENT OF DEFENSE CIVILIAN BIODEFENSE FUNDING, FY2001–FY2007 (IN $MILLIONS)

	FY2001 (actual)	*FY2002 (actual)*	*FY2003 (actual)*	*FY2004 (actual)*	*FY2005 (actual)*	*FY2006 (estimate)*	*FY2007 (budget)*
Biological Countermeasures	0	400	0	0	0	—[a]	—[a]
WMD Civil Support Teams	123	109	107	207	195	0	0
Cooperative Threat Reduction, BW Proliferation Prevention	12	17	54.7	67.8	68.7	60.8	68.4
Total DoD Civilian Biodefense Funding	**135**	**526**	**161.7**	**274.8**	**263.7**	—	—
Chemical and Biological Defense[b]	405	595	638	706	714.7	1049.4	959.1

[a] Exact numbers were unavailable due to inability of the DoD press office to provide information and a lack of clear and complete published information.

[b] This number was not included in the calculations because it includes many items that are not applicable to civilian biodefense, such as detectors, protective gear, vehicles, etc. It is listed as a reference for those interested.

Sources: Office of the Secretary Media Public Affairs, Department of Defense; Congressional Budget Office; AAAS Report on FY2007 Research and Development in DoD; DoD RDT&E Defense-Wide Budget http://www.dod.mil/comptroller/defbudget/fy2007/budget_justification/pdfs/rdtande/Vol_4_CBDP/CBDP_RDTE_DW.pdf;pg.178; DoD Offices of the Secretary of Defense Budget Justifications FY2003–FY2007 http://www.dod.mil/comptroller/defbudgetr/fy2007/budget_justification/pdfs/operation/O_and_M(CO)_Volume_I_PB_2007.pdf;pg.759

fense funding total and continues a general trend of incremental increases in funding since FY2001, excluding consideration of BioShield funds. About 88% of the proposed FY2007 funding is budgeted for agencies and programs within HHS and DHS, a figure similar to that of FY2006. While most departments and agencies are budgeted an increase in biodefense funds, the President is proposing that DHS and the National Science Foundation have civilian biodefense funding cuts for FY2007. DHS would experience the largest budget reduction compared to FY2006, mainly due to emergency funds provided to the department for its response to Hurricane Katrina that would not be present in FY2007. HHS would have the largest increase in biodefense funding, primarily for programs relating to the Strategic National Stockpile and for the support of advanced development of biological countermeasures by NIH. The President is requesting that two other agencies receive significant increases in their FY2007 budgets: USDA would receive an additional $127 million for its Food and Agriculture Defense Initiative, when excluding consideration of prior funds provided for the completion of the Ames, Iowa BSL-3 facility; and EPA would receive an additional amount of $54 million for its Water Sentinel and Homeland Security preparedness and response programs. As of FY2006, a total of $1.1 billion has been spent on Project BioShield.

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Exhibit No. 18

SELECT AGENTS

Note: Agents in bold denote human pathogens.

AGENT	CDC[1]	BSL[2]
BACTERIA:		
***Bacillus anthracis* (Anthrax)**	A	2/3
Botulinum neurotoxin producing species of *Clostridium* (Botulism)	A	2/3
***Brucella abortus* (Brucellosis)**	B	3
***Brucella melitensis* (Brucellosis)**	B	3
***Brucella suis* (Swine brucellosis)**	B	3
***Burkholderia mallei* (Glanders)**	B	2/3
***Burkholderia pseudomallei* (Melioidosis)**	B	2/3
"*Candidatus* Liberobacter" spp. (Huanglongbing [HLB], greening disease)		
***Francisella tularensis* (Tularemia, rabbit fever)**	A	3
Mycoplasma capricolum ssp. *capripneumoniae*		
Mycoplasma mycoides ssp. *mycoides small colony*		
Ralstonia solanacearum race 3, biovar 2 (Southern wilt, bacterial wilt, potato brown rot)		
Xanthomonas oryzae pv. *Oryzicola* (Rice blight)		
Xylella fastidiosa (citrus variegated chlorosis strain)		
***Yersinia pestis* (Plague)**	A	2/3
VIRUSES:		
African horse sickness virus		
African swine fever virus		
Akabane virus		
Alcelaphine herpesvirus type 1		
Bluetongue virus (exotic)		2
Camelpox virus		2
Cercopithecine herpesvirus 1 (Herpes B virus)		3/4
Classical swine fever virus		
Crimean-Congo hemorrhagic fever virus	A	4
Eastern equine encephalitis virus (EEE)	B	2/3
Ebola viruses	A	4
Foot-and-mouth disease virus		
Goatpox virus		2
Hendra virus (Equine morbillivirus)		4
Highly pathogenic avian influenza virus (bird flu)		3
Human enterovirus B (Swine vesicular disease)		
Japanese encephalitis virus		3
Lassa hemorrhagic fever virus	A	4
Lumpy skin disease virus		
Marburg virus (Marburg hemorrhagic fever)	A	4
Menangle virus		
Monkeypox virus		2
virulent Newcastle disease virus		
Nipah virus	C	
Peste-des-petits-ruminants virus		
Reconstructed 1918 influenza virus (Spanish flu)		3
Rift Valley fever virus		3
Rinderpest virus		
Sheeppox virus		2
South American hemorrhagic fever viruses:		
Flexal	A	3
Guanarito	A	4
Junin	A	4
Machupo	A	4
Sabia	A	4
Tick-borne encephalitis complex (flavi) viruses:		
Central European tick-borne encephalitis	C	3/4
Far Eastern tick-borne encephalitis	C	4
Kyasanur forest disease virus	C	4
Omsk hemorrhagic fever virus	C	4
Variola virus (Smallpox)	A	4
Venezuelan Equine Encephalitis virus	B	3
Vesicular stomatitis viruses (exotic)		3

AGENT	CDC[1]	BSL[2]
TOXINS:		
Abrin		2
Botulinum neurotoxins (Botulism)	A	2/3
***Clostridium perfringens* epsilon toxin (Gas gangrene)**	B	2
Conotoxins (cone shell venom)		2
Diacetoxyscirpenol (Type-A trichothecene mycotoxin)		2
Ricin (from *ricinus communis* [castor bean])	B	2
Saxitoxin (produced by certain algae)		2
Shiga-like ribosome inactivating proteins		2
Shigatoxin		2
Staphylococcal enterotoxins	B	2
T-2 toxin (a trichothecene mycotoxin)		2
Tetrodotoxin (from pufferfish)		2
FUNGI:		
***Coccidioides immitis* (Coccidioidomycosis, Valley fever)**		3
***Coccidioides posadasii* (Coccidioidomycosis)**		2
Synchytrium endobioticum (Potato wart disease)		
RICKETTSIA:		
***Coxiella burnetii* (Q fever)**	B	3
Ehrlichia [formerly *Cowdria*] *ruminantium* (Heartwater, Cattle Ehrlichiosis)		
***Rickettsia prowazekii* (Epidemic typhus)**	B	3
***Rickettsia rickettsii* (Rocky Mountain spotted fever)**		3
OTHER:		
Bovine spongiform encephalopathy agent (Mad cow disease)		2
Peronosclerospora philippinensis (Sugarcane/maize downy mildew disease)		
Schlerophthora rayssiae var *zeae*		

[1] CDC Bioweapons Agent Categories
(based on ease of spread and severity of impact [illness and death])
A: Agents that pose the highest risk to the public and national security
B: Agents that pose moderate risk to the public and national security
C: Agents that could be engineered to pose a serious risk in the future

[2] Bio-safety Level (BSL) Guidelines for Labs
(typical biosafety level used for non-clinical work, based on potential hazard of agent and activity; the use of agents in large quantities, at high concentrations, or in situations with a high risk for aerosolization should be performed at a higher BSL)
BSL-1: Not known to consistently cause disease in healthy adults
BSL-2: Associated with human disease, hazardous if exposed to percutaneous injury, ingestion, mucous membrane exposure
BSL-3: Indigenous or exotic agents which may cause serious or lethal disease as a result of aerosol exposure
BSL-4: Dangerous/exotic agents which pose high risk of aerosol-transmitted lab infections and life-threatening disease for which no vaccine or therapy is available; or related agents with unknown risk of transmission

Important Non-Select Agents
BSL-2: dengue hemorrhagic fever virus
Cat.B - BSL-2: Pathogenic *E. coli*, Pathogenic Vibrios, Salmonella, Shigella, Western equine encephalitis virus, *Cryptosporidium parvum*
Cat.B - BSL-3: multi-drug resistant *Mycobacterium tuberculosis*
Cat.C - BSL-3/4: Hantaviruses; BSL-3: SARS, West Nile virus

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Foreign Animal Diseases "The Gray Book" at http://www.vet.uga.edu/vpp/gray_book02/index.php

Exhibit No. 19

Economist.com WORLD

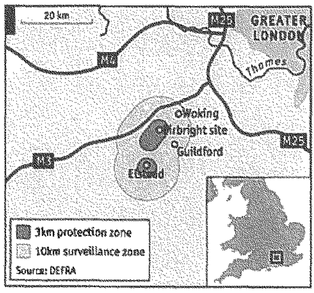
BRITAIN

Foot-and-mouth disease

Own goal

Aug 9th 2007
From The Economist print edition

Vaccines may prevent an epidemic. They may also have caused this outbreak



Source: DEFRA

BRITONS' most searing memories of their encounter with foot-and-mouth disease in 2001 are of the piles of animals slaughtered to try to stop its spread. Such a draconian policy might have been accepted had the disease been controlled quickly. But its ineffectiveness—more than 6m cows, sheep and pigs were culled before the disease was eradicated—led to widespread revulsion and a government rethink.

Just as in 2001, if an animal is thought to be infected, its herd will be culled and a quarantine zone set up (see map). But this time, unless the disease is stamped out quickly, animals nearby will also be vaccinated to create a "fire-break" across which it is unlikely to travel. Already 300,000 doses of vaccine have been ordered, so that if government vets decide that slaughter alone is unlikely to be effective, they can start vaccinating straight away.

Humans almost never catch foot-and-mouth and it rarely kills the cloven-hooved beasts it affects. But animals produce less milk and meat, so its economic effects are severe. It is also highly contagious: infected livestock produce the virus that causes it in large quantities, and transmit it through saliva, mucus, milk, faeces and even droplets in their breath.

Even so, only countries where foot-and-mouth is endemic, as in parts of Latin America, vaccinate all animals. One reason is cost: the disease is caused by a virus with seven main types and tens of sub-types, with a targeted vaccine needed for each strain and shots repeated, perhaps as often as twice a year. It is also because vaccinating damages exports. Places that are free from foot-and-mouth are unwilling to import vaccinated beasts, or fresh meat from them, because they may still carry the disease.

The fear of being shut out of foreign markets led to the British government's disastrous foot-dragging over vaccination in 2001. But that same year an outbreak in the Netherlands involving 26 farms was brought under control in just one month by vaccinating 200,000 animals. Though healthy, these beasts then had to be culled so that farmers could return to exporting without restrictions as soon as possible.

Not even eternal vigilance on imports can keep a country free of foot-and-mouth disease: the latest outbreak was apparently caused by a breach of bio-security at the Pirbright laboratory complex in Surrey, where government researchers keep the live virus for vaccine research and Merial, an American animal-health company, manufactures vaccine for export. Human action, accidental or deliberate, seems likely to have been involved.

Ironically, one reason for eschewing vaccination is that although it provides the best hope of dealing with outbreaks, maintaining the capacity to produce vaccine is itself a risky business. Many earlier episodes of foot-and-mouth in countries normally free from the disease have been caused by laboratory escapes; in 1970 a leak from Pirbright's isolation facilities was fortunately contained.

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Exhibit No. 20

How safe is biosafe?

By Richard Gray, Sunday Telegraph
Last Updated: 2:37am BST 14/08/2007
Page 1 of 3

If foot and mouth can escape from an animal laboratory, can we trust the high-security labs that study deadly human diseases? Richard Gray investigates

- **Foot and mouth latest**

Dressed in blue scrubs and disposable underwear, Simon Caidan cautiously transfers liquid into a series of vials inside the airtight cabinet in front of him. His arms are pushed up to his elbows in a pair of gloves sealed to the glass, preventing him from coming into contact with the potentially deadly material inside.

Britain complies with safety guidelines, but are they enough?

This is one of the most secure research laboratories in Britain, dealing with some of the world's most dangerous diseases. The threat posed by the pathogens kept here, on the outskirts of north London, is so great that the rooms are maintained at a lower air pressure than the outside to ensure nothing can escape when the doors are opened.

All the air passing through the building is filtered several times to strip it of even the finest particles, while staff have to remove all clothing before entering and must shower before leaving. If there is a spillage, the entire laboratory can be sealed and fumigated.

Yet, despite these formidable safety measures, it is from a laboratory similar to this that a foot and mouth virus is thought to have escaped, infecting nearby livestock. Initial reports into the outbreak in Normandy, Surrey, have pointed to a high-security laboratory in Pirbright, three miles away, shared by the government-funded Institute for Animal Health and a private drug firm, Merial UK.

The incident has sparked grave concerns about the state of the country's secure laboratories and the threat they pose. If a virus can escape from one such laboratory, can it happen again? And next time, could it be from a lab handling deadly human diseases?

In Britain, there are 15 "Containment Level Four" laboratories, the maximum biosecurity level, across the country. Each handles some of the deadliest organisms known to man and animals: diseases that are highly infectious, fatal even in low doses and impossible to treat.

"I am surprised there has been a release from a facility in the UK, of all places," said Dr Ingegerd Kallings, an expert on biosafety for the World Health Organisation and the Swedish Institute for Infectious Disease Control. "You have good regulations in place." For Dr Kallings, the escape of foot and mouth into the countryside around the Pirbright laboratory illustrates the weak link in the world's biosecurity measures: people.

"It comes down to a lax attitude among the staff," she said. "You can't really blame the age of a facility for an escape, as ultimately the biosecurity is not a technical issue."

What she, and other scientists, fear is that the tight regulations and safety measures can be rendered useless by carelessness. Adhering to safety protocols is tedious, and researchers can pick up bad habits or become complacent. Washing contaminated material down the wrong sink, for instance; carrying infected samples between rooms, or removing equipment from the laboratory before it has been properly decontaminated. All are hard to monitor and prevent.

Malicious behaviour is even harder to control, if a member of staff decides to smuggle a virus out of a facility. Doctors and scientists, as the recent terrorist attacks on Glasgow airport showed, can be radicalised like anyone else and many experts have pointed at the folly of keeping stocks of dangerous diseases so readily at hand. Investigators have still to rule out sabotage as the cause of the latest foot and mouth outbreak.

Then there are the facilities themselves. Can a simple household electric shower, as used in the National Institute for Medical Research where Mr Caidan works, for instance, remove all traces of a virus?

"Lab accidents happen more frequently than the public knows," says Ed Hammond, of the Sunshine Project, a non-profit-making organisation that monitors the use of biological agents. "They are not always as spectacular as the one in the UK, but I believe there's a real culture of denial about the scale of the problem."

In 2004, a Russian scientist working on an Ebola vaccine died after pricking her hand with a syringe, while in April 2005, a pandemic strain of Asian flu was released by a laboratory in America after it was accidentally put into test kits sent to scientists around the world. The last known case of smallpox occurred in 1978, when a researcher at Birmingham University was infected. No lab accident has resulted in the death of a member of the public... so far.

But campaigners fear that, with more and more research being carried out on these hazardous organisms, the risk of accidents and escapes is increasing. The viruses kept in Containment Level Four laboratories are among the most infectious. Just a few of the tiny organisms are needed to cause disease. Once out in the community, they would spread quickly, with little chance of controlling them, and there are effective treatments for few of them. In Britain, unlike other countries, researchers do not wear full-body protective suits, so staff are unprotected if a vial containing a virus is dropped.

At the National Institute for Medical Research, scientists are studying the deadly H5N1 avian flu virus. Samples from infected people are brought to the facility in London's Mill Hill for analysis. Researchers have also been working on the 1918 pandemic flu strain that killed about 50 million people. If this strain of the virus were to escape, it could cause a fresh pandemic, as virtually no one would have immunity.

"This is why the regulations have to be so strict," explains Mr Caidan, the head of safety for the site. "We are not just protecting our staff, but the environment and the general public."

The Medical Research Council, which funds the NIMR, has already asked for the biosafety procedures at the Institute to be checked in the wake of the foot and mouth outbreak. The laboratory is being refurbished, so Mr Caidan can provide visitors with a rare glimpse inside. Normally, just nine members of staff at a time are cleared to work inside the laboratory

Alarmingly, Britain is home to the world's highest concentration of dangerous pathogen laboratories, and has more than any country in Europe. France has just one, near Lyon, and Germany is building its third. America is the only other country with as many, but these are often in remote locations. The only stocks of foot and mouth, for example, are on Plum Island Animal Disease Centre, just off the coast of New York. In Britain, however, laboratories are near major population centres and farming communities. In some cases schools and playing fields flank the sites.

There are five laboratories in Britain, including the NIMR facility, that are authorised to handle the most dangerous human diseases. The MoD's Defence Science and Technology Laboratory, at Porton Down, on Salisbury Plain, Wiltshire, is one such and carries out high-level research on diseases such as anthrax and bubonic plague. The Health Protection Agency has its Centre for Emergency Preparedness and Response on the same site and also runs a similar laboratory at the Centre for Infections in Colindale, north London. The SARS virus, Lassa fever and the horrific Ebola virus, which causes massive bleeding in victims, are handled there.

There are another 10 laboratories, including Pirbright, licensed to handle highly dangerous animal pathogens such as foot and mouth, swine fever, avian flu and BSE.

So why are we taking the risk at all? "We need to carry out research on these organisms so we can understand them better and produce ways of treating them," says Prof Philip Duffus, an animal virologist at Bristol University. "We also need to handle samples for diagnosis of these diseases."

Biosecurity in Britain is governed by international standards set by the European Union and the WHO. Britain, however, has chosen to interpret these standards differently from other countries. Rather than using full body suits and masks in Level Four laboratories, work is carried out in sealed cabinets instead. As far as the law is concerned, both are equally safe. But Mr Caidan added: "Scientists who use suited systems feel more comfortable and prefer the suits to the cabinets."

While the investigation into how the foot and mouth virus escaped from the Pirbright site continues, there are now doubts as to whether the laboratory is still fit for purpose. There are also questions about whether liquid waste from the Merial buildings and the Institute for Animal Health laboratory was treated sufficiently to kill any virus it contained, and investigators are still examining whether the disease could have been carried off the site by a member of staff.

One senior laboratory safety expert who recently visited the Pirbright laboratories has also raised concerns about the ability of the ageing facilities to effectively maintain biosecurity. "What I saw was quite shocking" he said. "There are some good scientists there, but the facilities are so old that the chances of making a mistake are much greater than at more modern facilities."

Regardless of the outbreak's cause, the safety of Britain's high-security laboratories will have to be improved. The WHO will publish new international standards for containing dangerous pathogens next year. The fear of the escape of a deadly human virus is sending many a shiver down white-coated spines.

What is a virus?

- They are the smallest living organisms, yet despite their relative simplicity, viruses are responsible for some of our most terrifying diseases, including Ebola, Aids, flu, smallpox and yellow fever

- Viruses are about 1,000 times smaller than the width of a human hair

- They are composed of a string of genetic information packaged inside a protective protein "coat"

- Unlike bacteria, which manufacture toxins and can replicate themselves, viruses require a host

- They infect the hosts cells by injecting their genes inside and hijacking the cell's biological machinery to copy themselves

- Eventually the host cell will burst, releasing more virus that can infect other cells and spread to other hosts

- Viruses cannot be treated with antibiotics. Antiviral drugs do not kill viruses but prevent them from multiplying

- Vaccines against viruses train the body's immune system to detect and destroy invading viruses

- Viruses are killed by high temperatures, but some, such as foot and mouth, can survive in the environment without a host for weeks

Exhibit No. 21

BIOSECURITY

Reports Blame Animal Health Lab In Foot-and-Mouth Whodunit

Neglected, leaky pipes and England's record-setting wet summer likely combined to cause the country's recent outbreak of foot-and-mouth disease (FMD), according to two reports issued last week. The virus responsible probably escaped from a company, Merial, that grew vast amounts of it for vaccine production, the studies say. Yet the reports assign most of the blame for the outbreak to the Institute for Animal Health (IAH), a government lab at the same site in Pirbright that owned the aging network of underground wastewater pipes and was aware that it needed maintenance. IAH breached biosecurity in other ways as well, the reports found.

The findings are a blow to the reputation of IAH, a world-renowned FMD research center, says Andrew Mathieson, an environmental health expert at the University of the West of England in Bristol. But they should also serve as a more general warning. "My worry is: What about the many other research establishments of the same age?" he says.

Rapid government action helped contain the FMD outbreak, first confirmed on 3 August, to just two farms in Surrey (*Science*, 10 August, p. 732). Still, the National Farmers' Union puts the accident's economic impact at more than $100 million, and some politicians have called for resignations at the Department for Environment, Food and Rural Affairs (Defra), which oversees biosafety at IAH and also funds some 65% of its work.

Genomic comparisons of the outbreak virus to strains from Merial and IAH can't pinpoint from which of the two labs the virus escaped, according to the reports, one led by the U.K.'s Health and Safety Executive (HSE), a government agency, and the other by molecular epidemiologist Brian Spratt of Imperial College London. Still, the panels say, it's much more likely that the virus came from Merial, which grew it in two 6000-liter vats shortly before the accident, producing a million times more virus than IAH used in its small-scale experiments.

But how did it escape? The reports conclude that air leaks, contamination from solid waste, and foul play by terrorists or disgruntled employees are unlikely. Instead, both focus their suspicions on the site's wastewater system.

A two-step chemical strategy is used at Pirbright to prevent FMD from escaping in liquid waste. Both Merial and IAH first treat wastewater at their own buildings with a disinfectant such as citric acid. Then, a complex system of pipes takes the water to a shared effluent treatment plant, managed by IAH, where caustic soda is used to raise the pH to 12 and kill off any remaining virus during a 12-hour holding period. Finally, the liquid is released into the sewer.

Although the first treatment step probably killed off almost any leftover virus at IAH, it likely didn't inactivate the larger amounts in Merial's wastewater. The second treatment step would normally take care of that, but the network of pipes, pumps, and manholes leading to it suffered from leaks due to cracks, tree roots, and other problems. The reports hypothesize that live virus seeped into the soil as a result, especially because July's excessive rainfall may have caused the drains to overflow.

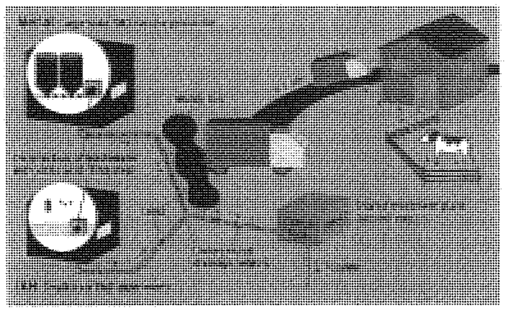
As it happened, construction crews were digging holes around the leaks at the time, and heavy trucks—without proper IAH oversight—drove through the presumably virus-laden mud. Some of these vehicles later took a road that went very close to the first infected farm. From there, the farmer may have carried the virus to his herd.

IAH, a part of the U.K. Biotechnology and Biological Sciences Research Council (BBSRC), owns the antiquated drainage system, the HSE report says. It was also aware of some of the network's problems. In fact, IAH, Defra, BBSRC, and Merial had debated an upgrade since 2003; the problem was money.

As to Merial's discharge of virus into its wastewater, HSE says this wasn't a breach of biosecurity, because Defra had approved the procedure used in the first disinfection step. But in a statement, IAH pointed its finger at Merial, suggesting that the company should have taken better care to inactivate any virus. Strangely, the Spratt report says, IAH didn't seem to know that Merial might release active virus into the system; biosafety officers from the lab and the company hardly ever talked.

Both panels question the wisdom of chemically inactivating wastewater altogether. Indeed, most modern labs use thermal inactivation—that is, pressure-cooking at 121°C—to destroy any pathogens, says Lee Thompson, a biosafety officer at the University of Texas Medical Branch in Galveston. Still, the second step, using caustic soda, "is very effective against FMD," Thompson says—but underground pipes that cannot be inspected "are a big problem."

Defra says it will adopt a range of recommendations to fix problems at Pirbright, such as keeping better track of visitors and making sure biosafety officers communicate. Merial has agreed not to grow live virus until U.K. authorities give it the green light. IAH, which was constructed in 1924, is due to be almost completely rebuilt by 2012, although some funding issues remain. Defra has also asked Health and Safety Commission chair Bill Callaghan to review the regulatory framework for animal pathogens. He is due to report by December. **–MARTIN ENSERINK**



Recipe for an outbreak. *The escaped foot-and-mouth disease virus (red) probably originated at vaccine manufacturer Merial, two reports say, but the Institute for Animal Health owns the leaky drainage system that presumably let the virus seep into the soil. Trucks may have then carried it close to a farm.*

SOURCE: J. NEWFIELD/SCIENCE

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Exhibit No. 22

Redundancy. A positive-pressure "space suit" is one of several precautions used to protect workers from the deadliest pathogens in a biosafety level 4 lab.

BIOSAFETY BREACHES

Accidents Spur a Closer Look at Risks at Biodefense Labs

Failure to report a *Brucella* infection and other problems at a Texas university have microbiologists searching for ways to ensure safety and public trust

An unreported infection with a dangerous pathogen and other biosafety breaches at a Texas university are fueling an already heated debate about safety at U.S. biodefense labs. The problems at Texas A&M University in College Station, which led federal officials to shut down the university's biodefense research this summer, follow a spate of accidents at other U.S. labs in the past few years. They also coincide with the accidental release of foot-and-mouth virus from a research facility in the United Kingdom that has shown the potential economic devastation that can result if a pathogen escapes. These events are bringing new urgency to a question raised soon after the United States began pouring money into biodefense research after the 2001 anthrax attacks: Are the nation's biodefense labs safe enough?

"Proponents insist there is a clean safety record. That is simply wrong. With some agents, it could have catastrophic consequences," says microbiologist Richard Ebright of Rutgers University in Piscataway, New Jersey, a critic of the biodefense expansion.

Although other scientists and biosafety experts say the extensive breakdown in procedures at Texas A&M is probably exceptional, they too worry that many incidents are going unreported. Next week, a congressional committee will examine the recent accidents and the biodefense buildup.

The scrutiny is sending tremors through university administrators and the microbiology community, which is struggling with how to both ensure safety and gain the public's trust. One idea under discussion is an anonymous national accident reporting system that would enable institutions to learn from one another's mistakes.

Winning public confidence could determine whether several proposed labs, such as one being built in Boston, will be allowed to operate at biosecurity level 4 (BSL-4), the highest level used to study the most dangerous pathogens. Community support will also likely play a role in which of five competing sites wins a planned $450 million BSL-4 national agro-biodefense lab funded by the Department of Homeland Security.

Some infectious disease experts worry that public hysteria fueled by watchdog groups over even relatively minor lab incidents will paradoxically make it harder to establish the atmosphere of trust that is essential to running a safe lab. "To ring all the bells and bring out the fire trucks is counterproductive," says virologist Clarence J. Peters of the University of Texas Medical Branch (UTMB) in Galveston. But there is room for improvement, he adds: "One of the biggest problems is transparency. I think we're all going to have to get past that."

Into the hot zone

To be sure, biosafety has come a long way in the past few decades. Before then, "there weren't a whole lot of rules, just a lot of common sense" about how to run an infectious disease lab, says virologist Charles Calisher of Colorado State University in Fort Collins, who says the biosafety officer's main message was: "Put that cigarette out; no more mouth pipetting." Peters notes that there were thousands of lab-acquired infections before the 1970s, when labs began installing hoods, shields around centrifuges, and other safeguards. In 1984, the U.S. National Institutes of Health (NIH) in Bethesda, Maryland, and Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, produced the first edition of a guidebook, called *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*), that pooled researchers' experiences and is now considered the Bible of safety.

Oversight became stricter after 2001 when federal agencies beefed up a regulation, called the select-agent rule, for the handling of pathogens such as anthrax and the Ebola virus that are potential bioweapons. The rule requires that lab workers get a security clearance for working on the roughly 80 select agents and toxins; that select-agent labs be inspected and workers undergo training; and that lab exposures and losses of select agents be reported to

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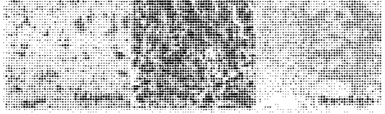

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2004: Three workers infected with tularemia, Boston University

2004: Ebola needle stick (no infection), USAMRIID

2004: Anthrax exposure (no infection), Children's Hospital, Oakland, CA

2004: Valley fever (*C. immitis*) infection, Medical College of Ohio

2005: Potential Q fever exposure, Rocky Mountain Labs, Hamilton, MT

2006: Brucellosis infection, Texas A&M

CREDITS (TOP TO BOTTOM): AP; CDC

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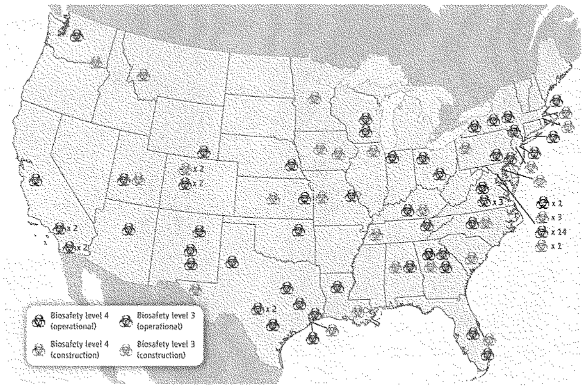
CDC. About 14,000 people at 400 labs now have select-agent authorization.

To date, the most serious biosafety breaches have occurred outside the United States, such as several SARS infections in Asia in 2003 and 2004 that killed one researcher and infected several people outside the lab and the death of a Russian lab worker from Ebola in 2004. And some potential exposures—such as animal bites, needle sticks, and glove tears—are inevitable, U.S. biosafety experts say. One of the worst recent accidents occurred at the U.S. Army Medical Research Institute of Infectious Diseases in Fort Detrick, Maryland, where a worker was exposed to the Ebola virus but didn't become infected. Others (see table, p. 1852) involved shipments of pathogens labeled nonpathogenic that turned out to be virulent. That happened with tularemia in Boston University in 2004, where three workers were infected. The incident was reported to local authorities and made public only after delays, adding to criticism of the proposed Boston BSL-4 lab (*Science*, 28 January 2005, p. 501).

The problems at Texas A&M, however, may be the most egregious to date. They first emerged in April when the school belatedly reported to CDC that in February 2006, a worker was infected with *Brucella* bacteria, a pathogen common in livestock that causes fever and fatigue in humans but is rarely fatal. This incident, like many others, was brought to light through public records requests by Edward Hammond of the Sunshine Project, a watchdog group in Austin, Texas. In June, after the Sunshine Project reported that three workers had tested positive for antibodies to the Q fever pathogen, CDC shut down all of Texas A&M's select-agent work. In an August investigation, CDC inspectors found a dozen serious violations, including unapproved experiments, lost samples, improper safety training, and lab workers without select-agent authorization (*Science*, 14 September, p. 1487).

Some observers suggest the Q fever antibody tests were not a major issue; none of the workers became ill, and two were apparently exposed before they joined the lab. But the *Brucella* case, which happened when a worker leaned into an aerosol chamber to clean it, is a clear violation of safe practices: The chamber should have been decontaminated with gas first, says Jonathan Richmond, a consultant in Southport, North Carolina, who oversaw biosafety at CDC in the 1990s. It has added to speculation that more incidents aren't being reported. Hammond has used open-records requests to dig up examples of exposures, equipment failures, and other near-misses at various labs that weren't publicly disclosed. He says they suggest other significant mishaps are hidden.

Researchers and biosecurity experts say serious infections would be difficult to hide from CDC. But some agree there is probably underreporting of mild infections and potential exposures. Workers who make a mistake are often embarrassed and may fear angering their supervisor, and institutions worry about the damage to their reputation, says Richmond.


Biosafety level 4 (operational)
Biosafety level 3 (operational)
Biosafety level 4 (construction)
Biosafety level 3 (construction)
x 2
x 2
x 2
x 2
x 2
x 3
x 1
x 3
x 14
x 1

Proliferation. Critics are worried about the potential for infections and escapes at biosafety level 4 (BSL-4) labs (five existing, at six least planned) and 84 existing and new BSL-3 biodefense labs, as compiled here by the Sunshine Project.

SOURCE: THE SUNSHINE PROJECT, WWW.SUNSHINE-PROJECT.ORG AS OF FEBRUARY 2006

"It's been a problem for a long time," he says. Supporting that suspicion, CDC, which has recorded about 20 accident reports a year since 2004, has received 32 reports since April 2007, possibly because of the publicity about Texas A&M, says a CDC spokesperson.

Although the multiple protocol violations at Texas A&M may be the exception, less extensive violations are not. A 2006 Department of Health and Human Services (HHS) Inspector General audit of security procedures found that 11 of 15 institutions had "serious weaknesses" such as unlocked doors and freezers and lax inventory records. Janet Shoemaker, public affairs director for the American Society for Microbiology in Washington, D.C., points out that schools have a strong incentive to adhere to the rules; since 2003, the HHS Inspector General has levied fines ranging from $12,000 to $150,000 on nine research institutions and companies for breaches such as unapproved select-agent shipments. Texas A&M is facing fines as high as $500,000 for each violation.

No public menace

One point of agreement among most scientists is that however scary these incidents sound—the mention of Ebola virus conjures the 1995 movie *Outbreak*, for example—the risk to the public is very low for most pathogens, for two reasons. First, there have been no known environmental escapes from BSL-4 labs since the early 1980s and only two workers are known to have become infected in BSL-4 labs, both outside the United States. Workers have many layers of protection, including positive-pressure "space suits," and realize the hazards of working with pathogens studied in BSL-4 labs, for which, by definition, there are no treatments.

Second, even if an agent studied in a BSL-4 lab did escape, most, with the exception of smallpox (which can only be studied at CDC), are not very transmissible. Anthrax doesn't spread person to person, for example. Ebola and other hemorrhagic fevers that have killed hundreds in Africa would likely never cause an outbreak in Western countries because hygiene and medical treatments are so much better, says Peters. (He also notes that many select agents, such as anthrax and Q fever, occur commonly in nature, so people

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can get infected without coming anywhere near a biodefense lab.)

Some scientists and biosafety experts are more worried about risks at BSL-3 labs, because the standards at these labs are not as stringent. But even most of these pathogens—with the exception of SARS, avian influenza, and 1918 flu—are not very communicable, and in any case vaccines and other treatments are available. At most, says infectious disease modeler Ira Longini of the University of Washington, Seattle, "the result could be a handful of cases and maybe deaths." Another exception is foot-and-mouth disease, which doesn't infect humans but is extremely contagious among animals; the escape in the United Kingdom, which has been tied to an outdated effluent treatment system, would be unlikely to occur at more modern facilities in the United States, Richmond says.

Peters worries that the "hysteria and witch hunting" by people like Hammond of the Sunshine Project is compromising safety by making lab workers worry that reporting potential exposures will get them fired. "People can't be terrified to report," agrees Jean Patterson of the Southwest Foundation for Biomedical Research in San Antonio, Texas, which runs a BSL-4 lab.

Safety check

So how can biosafety be improved? One proposal is an anonymous, mandatory reporting system for all laboratory accidents. Such a system would enable labs to learn from one another's mistakes, as do the data compiled on aviation accidents by the National Transportation Safety Board, says Gigi Kwik Gronvall of the Center for Biosecurity of the University of Pittsburgh Medical Center in Baltimore, Maryland, who co-authored a paper describing this proposal earlier this year in *Biosecurity and Bioterrorism*. "Other industries have gone through this," says Gronvall. The system would also capture lab exposures to pathogens not on the select-agent list, such as HIV and tuberculosis. Reporting these to NIH or CDC is not mandatory, Rutgers's Ebright notes.

But some microbiologists caution that reportable incidents should be well-defined, lest the system become glutted with minor mishaps. (Peters cites UTMB's recent decision to release, at a community group's request, a list of its 17 near-misses in the past 5 years.) Also important, says biosafety consultant W. Emmett Barkley of Bethesda, Maryland, reports should include not just bare facts but analysis, as CDC now provides for selected lab accidents in its *Morbidity and Mortality Weekly Report*.

A more radical idea is to require that BSL-3 and BSL-4 labs be licensed by the federal government. This would mean that all these labs, not just those working on select agents, would be inspected and they would be required to follow the same operating procedures. One supporter of this proposal, biosecurity expert Anthony Della-Porta of Geelong, Australia, says the problem now is that *BMBL* offers only general guidance. Others, such as Barkley, say institutions need flexibility, especially the many BSL-3 labs that don't do biodefense work.

There's one fact that nobody disputes: The risk of accidents in biosafety labs goes up with the number of workers. For that reason, watchdog groups and even some biodefense researchers lament the lack of analysis on whether all of the six planned BSL-4 and two dozen new BSL-3 biodefense labs are actually necessary to protect the nation from bioterrorism (see map). Says Gronvall: "Is there too much [biodefense research]? Without seeing the plan of action, it's hard to say."

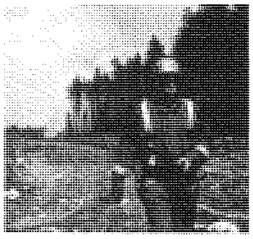
–JOCELYN KAISER

ECOLOGY

Setting the Forest Alight

To validate satellite data for carbon-emissions modeling, researchers this summer torched a jack-pine forest in Canada and tried to ignite a stand of larch in Siberia

KODINSK, RUSSIA—In July, as temperatures soared during a heat wave in eastern Siberia, scores of large fires flared through the region's dense pine forests. For 500 kilometers along the Amur River northwest of Lake Baikal, thick smoke blanketed the wilderness. Officials with Russia's famous airborne forest fire fighting service, Avialesookhrana, were tracking the wildfires at an airbase here in Kodinsk, a small city on the Amur. They were tense. To them it seemed bizarre that a team of international scientists had received permission to burn a patch of nearby forest. Even with every local helicopter and plane conscripted to serve their firefighting crews, millions of dollars' worth of timber was going up in smoke in wildfires. "It's not as though we don't have enough to worry about already," mused Oleg Mityagin, the overtaxed local Avialesookhrana boss. "We're in no position to help them if they lose control."



Safe distance. Douglas McRae checks out a gap in a pine forest during an experimental burn in Ontario, Canada.

Sixty kilometers to the west at the experimental site, a group of Russian, American, and Canadian researchers hoped to set a test fire that would thoroughly burn a hectare-sized patch of larch forest, Siberia's dominant conifer. Their aim was to quantify carbon emissions from fires in larch forests across Siberia, now inadequately documented, according to Douglas McRae, a forest-fire researcher with the Canadian Forest Service. McRae has been conducting experimental burns in Canada and Russia since 1999 as part of project FIRE BEAR (Fire Effects in the Boreal Eurasia Region), a research program aimed at studying forest-fire behavior, ecological effects, emissions, carbon cycling, and remote sensing.

Conceived in 1997, FIRE BEAR brings researchers from the U.S. Department of Agriculture (USDA) Forest Service and the Canadian Forest Service together with colleagues at the Siberian branch of the Russian Academy of Sciences' (RAS's) V. N. Sukachev Institute in Krasnoyarsk. As the group's previous studies have shown, extreme forest fires are growing more frequent in Siberia. And some models predict that climate change will bring dramatic warming—and more forest destruction—in eastern Siberia and other northern regions. The experimental burn, the FIRE BEAR team hoped, would yield direct observations to buttress satellite data and fill gaps in the models.

CREDIT: PAUL WEBSTER

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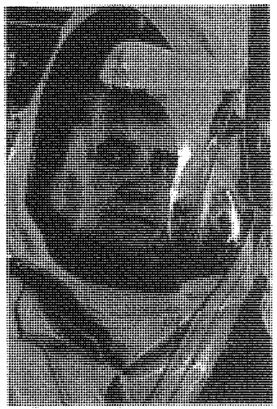
Exhibit No. 23

Oct 2, 5:15 PM EDT

Mishandling of Germs on Rise at US Labs

By LARRY MARGASAK
Associated Press Writer



AP Photo/Gary Emeigh

WASHINGTON (AP) -- American laboratories handling the world's deadliest germs and toxins have experienced more than 100 accidents and missing shipments since 2003, and the number is increasing as more labs do the work.

No one died, and regulators said the public was never at risk during these incidents. But the documented cases reflect poorly on procedures and oversight at high-security labs, some of which work with organisms and poisons that can cause illnesses with no cure. In some cases, labs have failed to report accidents as required by law.

The mishaps include workers bitten or scratched by infected animals, skin cuts, needle sticks and more, according to a review by The Associated Press of confidential reports submitted to federal regulators. They describe accidents involving anthrax, bird flu virus, monkeypox and plague-causing bacteria at 44 labs in 24 states. More than two-dozen incidents were still under investigation.

The number of accidents has risen steadily. Through August, the most recent period covered in the reports obtained by the AP, labs reported 36 accidents and lost shipments during 2007 - nearly double the number reported during all of 2004.

Likewise, the number of labs approved by the government to handle the deadliest substances has nearly doubled to 409 since 2004, and there are now 15 of the highest-security labs. Labs are routinely inspected by federal regulators just once every three years, but accidents trigger interim inspections.

In a new report by congressional investigators, the Government Accountability Office said little is known about labs that aren't federally funded or don't work with any of 72 dangerous substances the government monitors most closely.

"No single federal agency ... has the mission to track the overall number of these labs in the United States," said the GAO's report, expected to be released later this week. "Consequently, no agency is responsible for determining the risks associated with the proliferation of these labs."

The House Energy and Commerce investigations subcommittee plans hearings Thursday on the issue. The lab incidents have sparked bipartisan concern.

"It may be only a matter of time before our nation has a public health incident with potentially catastrophic results," said Rep. Bart Stupak, D-Mich., the panel's chairman.

The subcommittee's senior Republican, Ed Whitfield of Kentucky, added: "Currently, there is a hodgepodge system of federal oversight regulating the ... laboratories responsible for researching the deadliest germs and diseases. At Thursdays hearing, I expect to probe witnesses about how to improve oversight of these laboratories in a post 9-11 world."

Lab accidents have affected the outside world: Britain's health and safety agency concluded there was a "strong probability" a leaking pipe at a British lab manufacturing vaccines for foot-and-mouth disease was the source of an outbreak of the illness in livestock earlier this year. Britain was forced to suspend exports of livestock, meat and milk products and destroy livestock. The disease does not infect humans.

Accidents aren't the only concern. While medical experts consider it unlikely that a lab employee will become sick and infect others, these labs have strict rules to prevent anyone from stealing organisms or toxins and using them for bioterrorism.

The reports were so sensitive the Bush administration refused to release them under the Freedom of Information Act, citing an anti-bioterrorism law aimed at preventing terrorists from locating stockpiles of poisons and learning who handles them.

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-In Rockville, Md., ferret No. 992, inoculated with bird flu virus, bit a technician at Bioqual Inc. on the right thumb in July. The worker was placed on home quarantine for five days and directed to wear a mask to protect others.

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-In Albuquerque, N.M., an employee at the Lovelace Respiratory Research Institute was bitten on the left hand by an infected monkey in September 2006. The animal was ill from an infection of bacteria that causes plague. "When the gloves were removed, the skin appeared to be broken in 2 or 3 places," the report said. The worker was referred to a doctor, but nothing more was disclosed.

-In Fort Collins, Colo., a worker at a federal Centers for Disease Control and Prevention facility found, in January 2004, three broken vials of Russian spring-summer encephalitis virus. Wearing only a laboratory coat and gloves, he used tweezers to remove broken glass and moved the materials to a special container. The virus, a potential bio-warfare agent, could cause brain inflammation and is supposed to be handled in a lab requiring pressure suits that resemble space suits. The report did not say whether the worker became ill.

Other reports describe leaks of contaminated waste, dropped containers with cultures of bacteria and viruses, and defective seals on airtight containers. Some recount missing or lost shipments, including plague bacteria that was supposed to be delivered to the Armed Forces Institute of Pathology in 2003. The wayward plague shipment was discovered eventually in Belgium and incinerated safely.

The reports must be submitted to regulators whenever a lab suffers a theft, loss or release of any of 72 substances known as "select agents" - a government list of germs and toxins that represent the horror stories of the world's worst medical tragedies for humans and animals.

A senior CDC official, Dr. Richard Besser, said his agency is committed to ensuring that U.S. labs are safe and that all such incidents are disclosed to the government. He said he was unaware of any risk to the public resulting from infections among workers at the high-security labs, but he acknowledged that regulators are worried about accidents that could go unreported.

"If you're asking if it's possible for someone to not report an infection, and have it missed, that clearly is a concern that we have," Besser said.

Texas A&M's laboratory failed to report, until this year, one case of a lab worker's infection from Brucella bacteria last year and three others' previous infection with Q fever - missteps documented in news reports earlier this year. The illnesses are characterized by high fevers and flu-like symptoms that sometimes cause more serious complications.

"The major problems at Texas A&M went undetected and unreported, and we don't think that it was an isolated event," critic Edward Hammond said. He runs the Sunshine

Project, which has tracked incidents at other labs for years and first revealed the Texas A&M illnesses that the school failed to report.

Rules for working in the labs are tough and are getting more restrictive as the bio-safety levels rise. The highest is Level 4, where labs study substances that pose a "high risk of life-threatening disease for which no vaccine or therapy is available." Besides wearing wear full-body, air-supplied suits, workers undergo extensive background checks and carry special identification cards.

"The risk that a killer agent could be set loose in the general population is real," Hammond said.

In other lab accidents recounted in the reports, the Public Health Research Institute in Newark, N.J., was investigated by the FBI in 2005 when it couldn't account for three of 24 mice infected with plague bacteria. The lab and the CDC concluded the mice were cannibalized by other plague-infested mice or buried under bedding when the cage was sterilized with high temperatures.

The lab's director, Dr. David Perlin, told the AP it would be impossible for mice to escape from the building and said a worker failed to record their deaths.

"I feel 99 percent comfortable that was the case," Perlin said. "The animals become badly cannibalized. You only see bits and pieces. They're in cages with shredded newspaper. You really have to search hard with gloves and masks."

A worker at the Army's biological facility in Fort Detrick, Md., was grazed by a needle in February 2004 and exposed to the deadly Ebola virus after a mouse kicked a syringe. She was placed in an isolation ward called "The Slammer," but the Army said she did not become ill.

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In Decatur, Ga., a worker at the Georgia Public Health Laboratory handled a Brucella culture in April 2004 without high-level precautions. She became feverish months later and tested positive for exposure at a hospital emergency room in July. She eventually returned to work. The lab's confidential report defended her: "The technologist is a good laboratorian and has good technique."

In April this year at the Lovelace facility in Albuquerque, an African green monkey infected intentionally with plague-causing bacteria reached with its free hand and scratched at a Velcro restraining strap, cutting into the gloved hand of a lab worker. The injured worker at the Lovelace Respiratory Research Institute received medical treatment, including an antibiotic.

The National Animal Disease Center in Ames, Iowa, reported leaks of contaminated waste three times in November and December 2006. While one worker was preparing a pipe for repairs, he cut his middle finger, possibly exposing him to Brucella, according to the confidential reports.

A researcher at the CDC's lab in Fort Collins, Colo., dropped two containers on the floor last November, including one with plague bacteria.

A worker at Walter Reed Army Institute of Research-Naval Medical Research Center in Silver Spring, Md., sliced through two pair of gloves while handling a rat carcass infected with plague bacteria. The May 2005 report said she was sent to an emergency room, which released her and asked her to return for a follow-up visit.

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Exhibit No. 24

MSNBC.com

U.S. labs mishandling deadly germs

Number of accidents involving anthrax, other toxins increasing, review finds

The Associated Press

Updated: 10:39 a.m. ET Oct 2, 2007

WASHINGTON - American laboratories handling the world's deadliest germs and toxins have experienced more than 100 accidents and missing shipments since 2003, and the number is increasing steadily as more labs across the country are approved to do the work.

No one died, and regulators said the public was never at risk during these incidents. But the documented cases reflect poorly on procedures and oversight at high-security labs, some of which work with organisms and poisons so dangerous that illnesses they cause have no cure. In some cases, labs have failed to report accidents as required by law.

The mishaps include workers bitten or scratched by infected animals, skin cuts, needle sticks and more, according to a review by The Associated Press of confidential reports submitted to federal regulators. They describe accidents involving anthrax, bird flu virus, monkeypox and plague-causing bacteria at 44 labs in 24 states. More than two-dozen incidents were still under investigation.

The number of accidents has risen steadily. Through August, the most recent period covered in the reports obtained by the AP, labs reported 36 accidents and lost shipments during 2007 — nearly double the number reported during all of 2004.

Risk to public health

Research labs have worked for years to find cures and treatments for diseases. However, the expansion of the lab network has been dramatic since President Bush announced an upgrade of the nation's bio-warfare defense program five years ago. The National Institute of Allergy and Infectious Diseases, which funds much of the lab research and construction, was spending spent about $41 million on bio-defense labs in 2001. By last year, the spending had risen to $1.6 billion.

The number of labs approved by the government to handle the deadliest substances has nearly doubled to 409 since 2004. Labs are routinely inspected by federal regulators just once every three years, but accidents trigger interim inspections.

"It may be only a matter of time before our nation has a public health incident with potentially catastrophic results," said Rep. Bart Stupak, D-Mich., chairman of the House Energy and Commerce investigations subcommittee. Stupak's panel has been investigating the lab incidents and will conduct a hearing Thursday.

Lab accidents have affected the outside world: Britain's health and safety agency concluded there was a "strong probability" a leaking pipe at a British lab manufacturing vaccines for foot-and-mouth disease was the source of an outbreak of the illness in livestock earlier this year. Britain was forced to suspend exports of livestock, meat and milk products and destroy livestock. The disease does not infect humans.

Bioterrorism concerns

Accidents aren't the only concern. While medical experts consider it unlikely that a lab employee will become sick and infect others, these labs have strict rules to prevent anyone from stealing organisms or toxins and using them for bioterrorism.

The reports were so sensitive the Bush administration refused to release them under the Freedom of Information Act, citing an anti-bioterrorism law aimed at preventing terrorists from locating stockpiles of poisons and learning who handles them.

Among the previously undisclosed accidents:

- In Rockville, Md., ferret No. 992, inoculated with bird flu virus, bit a technician at Bioqual Inc. on the right thumb in July. The worker was placed on home quarantine for five days and directed to wear a mask to protect others.
- An Oklahoma State University lab in Stillwater in December could not account for a dead mouse inoculated with bacteria that causes joint pain, weakness, lymph node swelling and pneumonia. The rodent — one of 30 to be incinerated — was never found, but the lab said an employee "must have forgotten to remove the dead mouse from the cage" before the cage was sterilized.
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Other reports describe leaks of contaminated waste, dropped containers with cultures of bacteria and viruses, and defective seals on airtight containers. Some recount missing or lost shipments, including plague bacteria that was supposed to be delivered to the Armed Forces Institute of Pathology in 2003. The wayward shipment was discovered eventually in Belgium and incinerated safely.

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A senior CDC official, Dr. Richard Besser, said his agency is committed to ensuring that U.S. labs are safe and that all such incidents are disclosed to the government. He said he was unaware of any risk to the public resulting from infections among workers at the high-security labs, but he acknowledged that regulators are worried about accidents that could go unreported.

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Rules for working in the labs are tough and are getting more restrictive as the bio-safety levels rise. The highest is Level 4, where labs study substances that pose a "high risk of life-threatening disease for which no vaccine or therapy is available." Besides wearing full-body, air-supplied suits, workers undergo extensive background checks and carry special identification cards.

"The risk that a killer agent could be set loose in the general population is real," Hammond said.

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Exhibit No. 25

Help
Return to Headlines

The Atlanta Journal-Constitution
ajc.com

News

Congress probes labs' handling of germs: As CDC, other U.S. facilities work with deadly toxins, incidents raise concerns about safety measures.

Staff and wire reports
1,299 words
3 October 2007
The Atlanta Journal - Constitution
Main
A1
English
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Congressional investigators, worried that a rush to build more bioterror labs is putting the public at risk, are scrutinizing more than 100 reported accidents and incidents at U.S. laboratories since 2003.

But as more labs experiment on some of the world's deadliest germs, little is known about their activities and there is no federal agency responsible for examining the potential dangers of the current building boom, according to a draft report by the Government Accountability Office, the investigative arm of Congress.

"While the research conducted at these labs is certainly valuable, we must make sure that it does not pose a risk to the public health," said Rep. John Dingell, chairman of the House Energy and Commerce Committee, which will hold a hearing Thursday.

Dingell (D-Mich.) said the committee has found there is little information even about the number of labs operated in the U.S., let alone whether they are safely run. Several recent high-profile incidents have drawn bipartisan concern, as have plans for several new federally funded biolabs. The University of Georgia in Athens is one of five finalists for a major new federal animal disease lab called the National Bio and Agro-Defense Facility.

Thursday's hearing will explore, among other things, the hourlong power outage this summer that shut down key safety features at the Centers for Disease Control and Prevention's new high-containment lab building on Clifton Road. It also will look at CDC's role as one agency that oversees some of the nation's labs.

"The issues of safety and security are paramount," said Dr. Richard Besser, director of CDC's terrorism division. Besser, who is scheduled to testify Thursday, said he'll talk with the panel about the CDC's interest in forming an independent group to review the current system for overseeing labs.

Such a panel should include members of the public as well as scientists, he said. "It's really critical that the public have a voice ... in terms of feeling comfortable their communities are safe."

Lots more labs

At the committee's request, the CDC provided information on more than 100 lab incidents involving certain bioterror agents that had been reported to the agency from 2003 through August.

No one died, and regulators said the public was never at risk during the incidents. But the cases reflect poorly on procedures and oversight at high-security labs, some of which work with organisms and poisons that can cause illnesses with no cure. In some cases, labs have failed to report accidents as required by law.

The mishaps include workers bitten or scratched by infected animals, skin cuts, needle sticks and more, according to a review of confidential reports to federal regulators. The accidents involved anthrax, bird flu virus, monkeypox and plague-causing bacteria at 44 labs in 24 states.

The number of accidents has risen steadily. Through August, labs reported 36 accidents and lost shipments during 2007 --- nearly double the number reported during all of 2004.

Likewise, the number of labs approved to handle the deadliest substances has nearly doubled to 409 since 2004, and there are now 15 of the highest-security labs. Federal regulators inspect labs just once every three years, but accidents trigger interim inspections.

CDC officials note the lab incident list provided to Congress only covers reported cases involving specific bioterror agents. CDC has five incidents on the list it provided to Congress, but has had more than 33 other potential infectious disease lab incidents since January 2006 involving other germs. There also is the potential for labs to not report incidents, CDC officials said.

Lab accidents have affected the outside world: Britain's health and safety agency concluded there was a "strong probability" a leaking pipe at a British lab manufacturing vaccines for foot-and-mouth disease was the source of an outbreak of the illness in livestock earlier this year. Britain suspended exports of livestock, meat and milk products and destroyed livestock. The disease does not infect humans.

Plague and bird flu

Accidents aren't the only concern. While medical experts consider it unlikely that a lab employee will become sick and infect others, these labs have strict rules to prevent theft of organisms or toxins.

Among the previously undisclosed accidents:

In Decatur, a worker at the Georgia Public Health Laboratory handled a Brucella culture in April 2004 without high-level precautions. She became feverish months later, tested positive for exposure, then was successfully treated with antibiotics. Elizabeth Franko, the lab's director, said the unidentified sample had been sent from a hospital seeking help diagnosing a sick patient. As a result of the infection, the lab now takes greater precautions when handling unknown or risky samples, she said. "

In Rockville, Md., ferret No. 992, inoculated with bird flu virus, bit a technician at Bioqual Inc. on the right thumb in July. The worker was quarantined for five days and directed to wear a mask to protect others.

An Oklahoma State University in December could not account for a dead mouse inoculated with bacteria that causes joint pain, weakness, lymph node swelling and pneumonia. The lab said an employee "must have forgotten to remove the dead mouse from the cage" before the cage was sterilized.

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In Fort Collins, Colo., a worker at a CDC lab was conducting an inventory of a sample freezer when he found three broken vials of Russian spring-summer encephalitis virus 2004. Wearing only a laboratory coat and gloves, he used tweezers to remove broken glass and moved the materials to a special container. The virus, a potential bio-warfare agent, could cause brain inflammation and is supposed to be handled in a lab requiring pressure suits that resemble space suits. Dr. Casey Chosewood, CDC's safety director, said the worker never became ill and that the agency wasn't aware the sample was in the freezer until the incident.

Other reports describe leaks of contaminated waste, dropped containers with cultures of bacteria and viruses, and defective seals on airtight containers. Some recount missing or lost shipments, including plague bacteria that was supposed to be delivered to the Armed Forces Institute of Pathology in 2003. The wayward plague shipment was discovered eventually in Belgium and incinerated safely.

Rules for working in the labs are tough and are getting more restrictive. The highest is Level 4, where labs study substances that pose a high risk of life-threatening disease for which no vaccine or therapy is available. Besides wearing full-body, air-supplied suits, workers undergo extensive background checks and carry special ID cards.

"The risk that a killer agent could be set loose in the general population is real," said Edward Hammond, who runs the Sunshine Project, which has tracked incidents at other labs for years.

Atlanta Journal-Constitution staff writer Alison Young contributed to this article.

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ID: 0006824410 Type: Photo Name: MESHCDCLAB0707 01 Date: 10/03/2007 Page: A14 Edition: Main Pub: AJC Caption: KIMBERLY SMITH / Staff CDC's new Emerging Infectious Disease Lab lost its power for an hour this summer, raising concerns about its safety and backup. The CDC has since upgraded the facility.

Document ATJC000020071003e3a30001w

Exhibit No. 26

Los Angeles Times

October 3, 2007 Wednesday
Home Edition

Research into potent bioagents increases the risk; Hundreds of universities and labs have joined the study of toxic microbes. Since 2003, there have been 111 accidents.

BYLINE: Jia-Rui Chong, Times Staff Writer

SECTION: MAIN NEWS; National Desk; Part A; Pg. 1

LENGTH: 1434 words

The researcher at Texas A&M University had never been trained to handle Brucella, a bacterium included on the government's select list of potential bioweapon microbes.

Her work was in a different type of bacteria, but when asked to help clean a chamber that had been used to create an aerosol version of Brucella, she leaned inside and wiped it down.

The bacteria entered her body through her eyes, investigators later surmised. She was infected for more than a month before doctors diagnosed her with brucellosis and put her on a regimen of strong antibiotics.

The incident last year was part of a small but unsettling number of laboratory accidents that has followed a boom in research funding after the Sept. 11, 2001, terrorist attacks and the still-unsolved anthrax mailings that came a week later.

The burst of money has spread biodefense work to hundreds of university and research laboratories. In some cases, the labs have been ill-prepared to work on the exotic microbes.

"Universities aren't set up to handle these programs," said Edward Hammond, U.S. director of the Sunshine Project, a nonprofit group in Austin, Texas, that tracks information on biological weapons research. "I think we made a serious mistake putting 400 labs, thousands of people in the U.S., in the driver's seat behind biological weapons."

All told, there have been 111 cases involving potential loss of bioagents or human exposure reported since 2003 to the national Centers for Disease Control and Prevention or the U.S. Department of Agriculture.

The incidents include the potential exposure of 12 laboratory workers to live anthrax bacteria after an incorrect sample was sent to Children's Hospital Oakland Research Institute in 2004, the infection of three researchers at Boston University in 2004 after they mistakenly handled a sample of live tularemia bacteria, and the disappearance of a mouse infected with Q fever at Texas A&M in 2006.

Federal officials say that the overall number of incidents is small, and they emphasize that no one has died -- and that no one beyond laboratory workers has been infected.

"If you're looking at the total amount of work in these labs, it strikes me that 100 incidents is very low," said Dr. Richard E. Besser, director of the CDC's Coordinating Office for Terrorism Preparedness and Emergency Response. "Full investigations were done, and none of the events were thought to put the public at risk."

But Richard Ebright, a microbiologist at Rutgers University who has been monitoring biodefense safety issues, said that given the potential danger of the materials, the number of accidents is, in some ways, immaterial.

"Twenty-five incidents per year does not represent a good record," he said. "It only takes one incident in which a highly transmissible agent is introduced into a human population to produce a catastrophic loss."

Following the money

Before 2001, experts say much of biodefense research took place in government laboratories, such as the U.S. Army Medical Research Institute of Infectious Diseases at Ft. Detrick in Maryland. There, scientists in full-body suits worked in containment laboratories developing vaccines for some of the world's most hideous diseases, such as Ebola, Marburg hemorrhagic fever, anthrax, smallpox, tularemia and Lassa fever.

Then, everything changed. A week after the Sept. 11 attacks, letters containing anthrax spores began appearing around the country. Five people died and 17 others were infected.

The incident prompted Congress to dramatically increase biodefense funding. Research money from the National Institute of Allergy and Infectious Diseases, which administers a major portion of biodefense funding, has grown from $187 million in 2002 to $1.6 billion in 2006.

Scientists followed the money. The CDC now counts about 14,000 researchers registered to work with so-called "select agents."

Biodefense experts were worried from the beginning about the expansion.

Increasing the number of laboratories increased the chances of an accident, experts said. Ebright said that the expansion also raised the problem of spreading the deadly knowledge of bioagents to potential terrorists.

Some of the early fears have not materialized. For example, there have been no confirmed thefts or losses of bioagents.

"We're in a much better place now than we were four years ago," the CDC's Besser said. "Now we have really strong requirements about who is allowed to work with these agents and what kinds of safety and security are in place."

In 2002, new federal rules required biodefense researchers to register their labs with the CDC or USDA to work with the agents, and pass a Department of Justice background check. They were also required to devise safety plans and report accidents to the government.

Still, concerns linger that the rules are inadequate. Congress has begun investigating the issue, and a hearing in Washington is scheduled for Thursday.

"There are no clear rules about training, ability or the orientation of the lab to handle these matters," said Rep. John D. **Dingell** (D-Mich.), chairman of the House Energy and Commerce Committee.

"There are bills for funding and for research, yet nobody knows what regulation there is, how the regulations work and whether they are safe," he said. "There is a culture of secrecy."

The results of government inspections have not been encouraging. A 2006 report by the inspector general of the Department of Health and Human Services found 11 out of 15 universities did not fulfill all the federal requirements. Several universities kept sloppy inventory records, and inspectors could not identify who was gaining access to the pathogens, according to the report.

Institutions working on animal and plant pathogens did worse. None of the 10 institutions described in a 2006 report by the USDA inspector general met all standards. Many had not updated their lists of people with access to the pathogens and had failed to fully train their staffs.

Potential for disaster

Many of the accidents have been relatively mundane. Most would be small events if not for the danger of the agents involved.

In May, a researcher at the University of Texas Health Science Center at Houston was working with anthrax in a centrifuge. When the machine began clanking, the researcher opened the cover and saw liquid spilled inside.

She and three others in a nearby room tested negative for anthrax, and no spores were found in the lab, university officials said.

"It was a rookie mistake," said Robert Emery, assistant vice president for safety, health, environment and risk management at UT Houston. "We exist to teach people to treat and prevent disease. Part of that is a lack of knowledge about technique and learning it."

Among the most serious incidents were the infections of three researchers at Boston University in 2004. They thought they were working on an inactivated vaccine strain of the bacterium Francisella tularensis, but actually were handling a virulent form that had been mistakenly sent by another laboratory.

The researchers all recovered, but it took months for doctors to diagnose their potentially fatal disease because its symptoms -- coughs, fever, headaches -- are common.

The Brucella case at Texas A&M turned out to be only the beginning of the university's troubles. When the CDC began investigating in April -- a year after the incident -- the university disclosed that three lab workers had blood tests in 2006 showing higher-than-normal levels of antibodies for Q fever, a disease caused by the bacterium Coxiella burnetii.

The researchers never showed any symptoms, so the university thought it did not have to report the cases, the university's interim president Eddie J. Davis told reporters in July.

The CDC found other problems, and on Aug. 31 suspended all work with select agents at the university, the first and only suspension issued by the agency.

Despite the punishment, Hammond, of the Sunshine Project, said the case was another example of how the biodefense program had grown too fast and too large for the government to adequately manage.

The system "is not really working," he said. "The explosion of biodefense programs is creating dangers."

Dr. Alan Barbour, a UC Irvine professor who directs a federally funded regional center for biodefense and emerging diseases, said national training standards must be adopted for bioagents.

"I'm a physician, and I'm used to dealing with people in the hospital," Barbour said. "If you make a mistake, someone could die. I think some people are not used to handling things that way. They're going to have to learn."

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jia-rui.chong@latimes.com

Exhibit No. 27

WSJ.com THE WALL STREET JOURNAL. ONLINE

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October 3, 2007

Lab Toxin Mishaps Rise

Missing Shipments, Accidents Top 100 In U.S. Since 2003

ASSOCIATED PRESS
October 3, 2007

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WASHINGTON -- U.S. laboratories handling the world's deadliest germs and toxins have experienced more than 100 accidents and missing shipments since 2003, and the number is increasing as more labs do the work.

No deaths have been reported as a result of the incidents, and the mishaps never put the public at risk, regulators said. But the documented cases reflect poorly on procedures and oversight at high-security labs, some of which work with organisms and poisons that can cause illnesses with no cure. In some cases, labs have failed to report accidents as required by law.

The mishaps include workers' being bitten or scratched by infected animals, skin cuts, needle sticks and more, according to a review by the Associated Press of confidential reports submitted to federal regulators. They describe accidents involving anthrax, bird-flu virus, monkey pox and plague-causing bacteria at 44 labs in 24 states. More than two dozen incidents were still under investigation.

The number of accidents has risen steadily. Through August, the most recent period covered in the reports obtained by the AP, labs reported 36 accidents and lost shipments this year -- nearly double the number reported during all of 2004.

At the same time, the number of labs approved by the government to handle the deadliest substances has nearly doubled to 409 since 2004, and 15 are of the highest security level. Labs are routinely inspected by federal regulators just once every three years, but accidents trigger interim inspections.

In a new report by congressional investigators, the Government Accountability Office said little is known about labs that aren't federally funded or don't work with any of 72 dangerous substances the government monitors most closely.

"No single federal agency... has the mission to track the overall number of these labs in the United States," said the GAO report, expected to be released this week. "Consequently, no agency is responsible for determining the risks associated with the proliferation of these labs."

The House Energy and Commerce investigations subcommittee plans hearings on the issue tomorrow. The lab incidents have sparked bipartisan concern.

"It may be only a matter of time before our nation has a public-health incident with potentially catastrophic results," said Rep. Bart Stupak (D., Mich.), the panel's chairman.

The subcommittee's senior Republican, Ed Whitfield of Kentucky, said: "Currently, there is a hodgepodge system of federal oversight regulating the...laboratories responsible for researching the deadliest germs and diseases.... I expect to probe witnesses about how to improve oversight of these laboratories in a post-9/11 world."

Lab accidents have affected other countries, too.

The United Kingdom's health and safety agency concluded there was a "strong probability" a leaking pipe at a U.K. lab manufacturing vaccines for foot-and-mouth disease was the source of an outbreak of the illness in livestock earlier this year. Britain was forced to suspend exports of livestock, meat and milk products and destroy livestock. The disease doesn't infect humans.

Accidents aren't the only concern. While medical experts consider it unlikely that a lab employee will become sick and infect others, these labs have strict rules to prevent anyone from stealing organisms or toxins and using them for bioterrorism.

The reports were so sensitive the Bush administration refused to release them under the Freedom of Information Act, citing an antibioterrorism law aimed at preventing terrorists from locating stockpiles of poisons and learning who handles them.

Among the previously undisclosed accidents:

In Rockville, Md., ferret No. 992, inoculated with bird-flu virus, bit a technician at Bioqual Inc. on the thumb in July. The worker was placed on home quarantine for five days and directed to wear a mask to protect others.

An Oklahoma State University lab in Stillwater in December couldn't account for a dead mouse inoculated with bacteria that causes joint pain, weakness, lymph-node swelling and pneumonia. The rodent -- one of 30 to be incinerated -- was never found, but the lab said an employee "must have forgotten to remove the dead mouse from the cage" before the cage was sterilized.

In Albuquerque, N.M., an employee at the Lovelace Respiratory Research Institute was bitten on the hand by an infected monkey in September 2006. The animal was ill from an infection of bacteria that causes plague. "When the gloves were removed, the skin appeared to be broken in two or three places," the report said. The worker was referred to a doctor, but nothing more was disclosed.

In Fort Collins, Colo., a worker at a federal Centers for Disease Control and Prevention facility found, in January 2004, three broken vials of Russian spring-summer encephalitis virus. Wearing only a laboratory coat and gloves, he used tweezers to remove broken glass and moved the materials to a special container. The virus, a potential bio-warfare agent, could cause brain inflammation and is supposed to be handled in a lab requiring pressure suits that resemble space suits. The report didn't say whether the worker became ill.

Other reports describe leaks of contaminated waste, dropped containers with cultures of bacteria and viruses and defective seals on airtight containers. Some recount missing or lost shipments, including plague bacteria that was supposed to be delivered to the Armed Forces Institute of Pathology in 2003. The wayward plague shipment was discovered eventually in Belgium and incinerated safely.

The reports must be submitted to regulators whenever a lab suffers a theft, loss or release of any of 72 substances known as "select agents" -- a government list of germs and toxins that represent the horror stories of the world's worst medical tragedies for humans and animals.

A senior CDC official, Richard Besser, said his agency is committed to ensuring that U.S. labs are safe and that all such incidents are disclosed to the government. He said he was unaware of any risk to the public resulting from infections among workers at the high-security labs, but he acknowledged that regulators are worried about accidents that could go unreported.

"If you're asking if it's possible for someone to not report an infection, and have it missed, that clearly is a concern that we have," Dr. Besser said.

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